

REGISTRATION

2724-796

Vol.3

# Material Sent for Data Extraction

Reg. # 2724-796

Description: \_\_\_\_\_

☒ Material(s) Sent to Data Extraction Contractors:

☒ New Stamped Label Dated 9-8-11

☐ Notification Dated \_\_\_\_\_

☒ New CSF(s) Dated 8-15-08

☐ Other: \_\_\_\_\_

☒ Decision #: 450419

☐ Other Action/Comments: \_\_\_\_\_

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Carmen Rodia

Phone: (703) 306-0327 Division: RD/IB

Date: 9-8-11



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460-0001

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

September 8, 2011

Mr. James McFadden, Ph.D.,  
Senior Regulatory Project Manager  
Wellmark International  
1501 East Woodfield Road, Suite 200 West  
Schaumburg, IL 60173-5417

**Subject: Amended Reregistration Label**  
**Product Name: RF2042 [CDSO]**  
**EPA Registration Number: 2724-796**  
**EPA Decision Number(s): D410828**  
**Your Resubmission Dated August 12, 2011**

Dear Mr. McFadden:

The Agency, in accordance with the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, has completed reviewing all of the information submitted with your application to support the reregistration of the referenced product in connection with the **RED for Piperonyl Butoxide**, and has concluded that your submission is acceptable. In addition, please note that the record for this product currently contains the CSF listed below. Any previously dated CSFs are superseded.

- Basic CSF, dated August 15, 2008

**PLEASE NOTE:** This product is not being reregistered under sections 3(c)5 and 4(g) of FIFRA at this time.

A copy of your label stamped "Accepted" is enclosed for your records. Products shipped after 12 months from the date of this amendment or the next printing of the label whichever occurs first, must bear the new revised label. Your release for shipment of the product bearing the amended label constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with section 6(e) of FIFRA.

If you have any questions about this letter, please contact Mr. Carmen J. Rodia, Jr. at (703) 306-0327 or via e-mail at [Rodia.Carmen@epa.gov](mailto:Rodia.Carmen@epa.gov) or Mr. Richard J. Gebken at (703) 305-6701 or via e-mail at [Gebken.Richard@epa.gov](mailto:Gebken.Richard@epa.gov) during the hours of 9:00 A.M. to 5:30 P.M. EST.

Sincerely Yours,

Richard J. Gebken  
Product Manager (10)  
Insecticide Branch  
Registration Division (7504P)

Enclosure: Label stamped "Accepted"  
002724-00796 D410828

## RF2042 [CDSO]

For Toy (6-12 lbs.), Small (13-31 lbs.), Medium (32-55 lbs.), Large (56-80 lbs.), and Extra Large (81 lbs. and over) Dogs

[Flea & Tick & Mosquito][Treatment] [and] Control for Dogs and Puppies (6 months of age or older)]

Effective on indoor and outdoor dogs

([1][3][4][6] monthly treatments) ]1][3][4][6] Months Supply [24][48] doses

Each tube [applicator] kills fleas & ticks for 3 weeks] and [kills and repels mosquitoes for 3 to 4 weeks]

]Protects for up to ]Four/4] Weeks[[One month[[Four/4 Week [Flea[[Tick[[Mosquito] Treatment]

]Aids in Control of Ticks for up to 30 days]

Contains an Insect Growth Regulator (IGR) to kill flea eggs and prevent flea development for

]more than 10 weeks] up to ]75 days][2.5 months]

]Starts Killing Fleas and Ticks within 15 minutes]

]Kills 85% of ticks within 48 hours]]Kills more than 50% of fleas in 2 hours[

]Dual Action kills adult fleas and prevents flea development]

]Breaks Flea Life Cycle for ]more than 10 weeks] up to [75 days][2.5 months]

]Controls flea reinfestation for [more than 10 weeks] up to [75 days][2.5 months]

]Kills fleas, ticks, mosquitoes, flea eggs and flea larvae] ]Dual protection (against fleas and ticks)[

Kills the Deer Tick, which may transmit Lyme Disease

Kills and Repels mosquitoes (a major carrier of canine heartworm)

[With ]S-Methoprene[ Insect Growth Regulator [IGR[ to Break Flea Life Cycle]

Convenient, easy to use ACCU-TIP DISPENSER ]applicator][tube]

Spreads naturally with dog's movement (skin and hair oils)

]Formula]]Contains lanolin for coat conditioning]

]Water Resistant[ [to keep killing fleas and ticks in humid and wet conditions]

]Fast Acting]]Long Lasting]]Kills Fleas and Ticks by Contact]

]Easy to use] Longer applicator tip for easy application to long-haired dogs

]Fresh]]Clean[[[Scent[[Smell]

]Reapply monthly] [Suitable for year-round use]]Month] sticker for home calendar

]Satisfaction guaranteed or your money back[

Alternate Applicator claims: Unique applicator [tube[ with flow control

]no drip]]no mess[[application[[applicator][tube]

(Front or Back panel)

### ACTIVE INGREDIENTS:

Etofenprox (CAS # 80844-07-1) ..... 30.0%

S-Methoprene (CAS # 65733-16-6) ..... 3.6%

Piperonyl Butoxide (CAS # 51-03-6)\* ..... 5.0%

OTHER INGREDIENTS: ..... 61.4%

TOTAL ..... 100.0%

\*(butyl carbityl) (6-propylpiperonyl ether) and related compounds

**KEEP OUT OF REACH OF CHILDREN**

**CAUTION**

See Back Panel for [Ingredients and] Additional Precautionary Statements

**NET CONTENTS:** One: 0.05 fl oz (1.5 cc) Applicator [tube[ (Toy Dogs)/0.10 fl oz (3.0 cc) Applicator [tube[ (Small Dogs)/0.15 fl oz (4.5 cc) Applicator [tube[ (Medium Dogs)/0.20 fl oz (6.0 cc) Applicator [tube[ (Large Dogs)/0.30 fl oz (9.0 cc) Applicator [tube[ (Extra Large Dogs)/

EPA Reg. No. 2724-796

EPA Est. No.

[RF2042 [CDSO] prevents flea eggs from developing into adult fleas [more than 10 weeks[ for up to [75 days][2.5 months]. RF2042 [CDSO] also kills fleas and ticks for 3 weeks and kills and repels mosquitoes for 3 to 4 weeks.]

**DIRECTIONS FOR USE:** It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

**IMPORTANT! READ ENTIRE LABEL BEFORE EACH USE. USE ONLY ON DOGS OR PUPPIES (6 MONTHS OF AGE OR OLDER). DO NOT USE ON OTHER ANIMALS!**

**USE RESTRICTIONS:**

For indoor use only.

Do not apply this product to puppies less than 6 months of age.

Do not reapply this product for 30 days unless retreatment is required, but not sooner than 8 days after the initial treatment. Do not retreat more than 1 time per month.

RF2042 [CDSO] works by application directly to the dog's skin, not to the hair. When applying, manually push aside dog's hair to allow direct application to the skin. Do not get this product in dog's eyes or mouth.

[(Note: Application now assumes one applicator per animal per application)]

[Note: Each package contains sufficient tubes/applicators for [X] applications]

**FOR [TOY][SMALL] SIZE DOGS**

1. Bend at perforation and tear off first applicator [tube]. [
2. Hold applicator [tube][and bend area of plastic at perforation, tear off and discard.] Hold applicator [tube] upright and snap tip back, away from face and body.
3. The dog should be standing for easy application. RF2042 [CDSO] should be applied evenly to [two spots](toy dogs)[three spots](small dogs) on the top of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the tube on the skin and gently squeeze to expel a portion of the solution on the skin. Do not apply an excessive amount of the solution at any one spot that could cause some of the solution to run off the side of the dog.
4. Do not spread RF2042 [CDSO] by hand over the dog. Although the dog's skin and hair oils will naturally distribute the application over the entire dog, brushing the dog 12-24 hours after application will help to distribute the material over the skin..
5. Discard empty [tube][applicator] as described in Storage and Disposal

[Note: Each package contains sufficient tubes/applicators for [X] applications]

**FOR [MEDIUM][LARGE][EXTRA LARGE] DOGS**

1. Bend at perforation and tear off first applicator [tube]. [(Note – multi-application pack)]
2. Hold applicator [tube][and bend area of plastic at perforation, tear off and discard.] Hold applicator [tube] upright and snap tip back, away from face and body
3. The dog should be standing for easy application. Apply RF2042 [CDSO] evenly to four or five spots on the top of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the tube on the skin and gently squeeze to expel a portion of the solution on the skin. Do not apply an excessive amount of the solution at any one spot that could cause some of the solution to run off the side of the dog.

**[Alternate Directions for Use for multi-tube application]**

- 3 The dog should be standing for easy application. Using the first applicator [tube], apply RF2042 [CDSO] evenly to four or five spots on the top of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the applicator [tube] on the skin and gently squeeze to expel a portion of the solution on the skin. Do not apply an excessive amount of the solution at any one spot that could cause some of the solution to run off the side of the dog. Using the second applicator [tube], apply as indicated for first applicator [tube] except start application at base of tail and apply on top of the back to the shoulder.
- 4 Do not spread RF2042 [CDSO] by hand over the dog. Although the dog's skin and hair oils will naturally distribute the application over the entire dog, brushing the dog 12-24 hours after application will help to distribute the material over the skin..
- 5 Discard empty [tube][applicator] as described in Storage and Disposal

RF2042 [CDSO] is most effective when used as part of a total flea and tick management program. Use other [Brand Name ] products registered for residential area control of these pests in conjunction with this treatment. Monthly treatments are required for optimal control and prevention of fleas.

[The successive feeding activity of fleas on pets may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). Treatment of pets with RF2042 [CDSO] rapidly kills fleas and may reduce the incidence of this condition.]

[RF2042 [CDSO] is water resistant and remains efficacious following exposure to rainfall or swimming.]

TREATMENT SCHEDULE			
Dosage: 1 applicator every 30 days per dog			
Pet's Name	First Treatment Date	Second Treatment Date (30 Days From 1 <sup>st</sup> )	Third Treatment Date (30 Days From 2 <sup>nd</sup> )

Reminder: I purchased RF2042 [CDSO] from: \_\_\_\_\_

NOTES: \_\_\_\_\_

Treatment table can be expanded based on package size. (6 months)

**STORAGE and DISPOSAL:** **Pesticide Storage:** Keep this product in its tightly closed original container, when not in use. Store in a cool, dry (preferably locked) area that is inaccessible to children and animals. **Container Disposal:** If **empty:** Do not reuse container [tube][applicator]. Place in trash or offer for recycling if available. If **partially filled:** Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

**PRECAUTIONARY STATEMENTS**

**HAZARDS TO HUMANS AND DOMESTIC ANIMALS - CAUTION**

**DO NOT USE ON PUPPIES LESS THAN 6 MONTHS OF AGE.** For external use only. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Repeated exposure to etofenprox can cause skin irritation. Consult a veterinarian before using this product on debilitated, aged, pregnant, nursing, or animals on medication. Sensitivities may occur after using ANY pesticide product for pets. If signs of sensitivity occur, bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.

**FIRST AID**

If in eyes

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after first 5 minutes, then continue rinsing
- Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. For additional information on this pesticide product (including health concerns, medical emergencies or pesticide incidents), you may call 1-800-XXX-XXXX, 24 hrs/day, 7 days/wk.

**WARRANTY AND CONDITIONS OF SALE:**

Seller warrants that this product conforms to the chemical specifications expressed on the label. To the extent consistent with applicable law, Seller makes no other warranties, and disclaims all other warranties, express or implied, including but not limited to warranties of merchantability and fitness for the intended purpose. To the extent consistent with applicable law, seller's liability for default, breach, or failure under this label shall be limited to the amount of the purchase price. To the extent consistent with applicable law, Seller shall have no liability for consequential damages.

In case of emergency or for product information, call 1-800-xxx-xxxx.

Wellmark International  
1501 E. Woodfield Road. 200W  
Schaumburg, Illinois 60173

[URL]

Made in USA

## Decision Information for 2724-796

Decision Seq: 450419

Action Code: 875 Pre-DCI RED mitigation, D

Decision Status

FFS Start Date

Tentative Ind: No

FFS Original Decision:

Tracking

Due Date: 23-Nov-2010

75-Day Due Date:

FFS EUP Decision:

Create Resubmission

OPP Target Due Dt:

21-Day Screen Dt:

FFS Primary Decision:

FFS Letters

Negotiated Due Dt:

Start/Stop Clock

FQPA Clock:

New Documentation

Registrant



Product Rereg Ing:

Days Elapsed:

Action Code History

Response Due Date:

Secondary Decision

Current Status: PENDING (31 Aug-2011)

Decision Comments

Payment

Unmatched Payments

75 Day Letters

Meetings &amp; Milestones

FFS Information

FFS Negotiated Due Dates

OPP Target Due Date

Decision Ownership

Receipts

Data Package

Reduced Risk

Receipts	Staff Member	Reg/DCI Number	Submission Due Dt	Response
S: 912537	Rodia, Carmen	2724-796	12-Aug-2011	PENDING

Submission of amended reregistration label.

S: 897700	Rodia, Carmen	2724-796	23-Nov-2010	OBJECTION - LABEL DEFICIENCY
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Pre-RED mitigation label amendment

Viewing Record 1 of 1





**Re: 2724-796 REREGISTRATION LABEL PER THE AUGUST 2, 2011 EPA LETTER**

Carmen Rodia to: Nancy Huebl  
Cc: Richard Gebken, James McFadden  
Bcc: Carmen Rodia

08/15/2011 08:25 AM

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History: This message has been replied to.

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Nancy, thanks for sending me an e-copy of the pending resubmission; however, you must submit the amended label, application form and transmittal through EPA's front-end office in order to properly accept your submission. Please submit it in hard copy and the label review will be reviewed as it is assigned. Regards, Carmen Rodia.

Carmen J. Rodia, Jr.  
Environmental Protection Specialist  
U.S. EPA, Office of Pesticide Programs,  
Office of Chemical Safety and Pollution Prevention,  
Registration Division, Insecticide Branch  
1200 Pennsylvania Avenue, N.W. (7504P)  
Washington, DC 20460-0001  
(703) 306-0327 (tel)  
(703) 308-0029 (fax)  
Rodia.Carmen@epa.gov

Deliveries: One Potomac Yard (South Building)  
2777 South Crystal Drive  
Arlington, VA 22202-4501

Nancy Huebl Good afternoon Carmen, Jim asked me to revise... 08/12/2011 04:11:32 PM

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From: Nancy Huebl <NHuebl@central.com>  
To: Carmen Rodia/DC/USEPA/US@EPA  
Cc: James McFadden <jmcfadden@central.com>  
Date: 08/12/2011 04:11 PM  
Subject: 2724-796 REREGISTRATION LABEL PER THE AUGUST 2, 2011 EPA LETTER

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Good afternoon Carmen, Jim asked me to revise the above label per your August 2, 2011 Request for Updated Reregistration Label for RF2042 [CDSO]. I have attached two copies, one hilited for your convenience in viewing where revisions were made, that one also has an explanatory cover sheet. Additionally, there is a clean copy for stamped approval. There was one comment per your letter where we did not revise the label per the comment, #6 – Pesticide Disposal. Per Pg. 13-14 of the Label Review Manual, Pesticide Product Disposal Statements: Pesticide products that are not hazardous wastes...and that are registered for all uses other than household or residential should bear the following..."Wastes resulting from the use of this product must be disposed of..." (which is what you asked us to change to). This product is a dog topical, a household/residential use pattern and PR Notices 2001-6/2007-1 apply to the pesticide disposal for this product and the language already on the label is appropriate. This is also documented on page 13-9 LRM Table 2 – Non-pressurized container. Regarding the nonrefillable PRN, this product is exempt from PRN 2007-4 as it is a single use vial that is destroyed when product is applied. Please call Jim or me if you have any questions or need anything further. Have a great weekend.  
Nancy Huebl

Sr. Registration Specialist  
Wellmark International  
847-330-5376

Disclaimer: This communication and any attachments contain private, confidential, privileged and/or proprietary information intended solely for the Recipient(s) named above. If you are not the intended Recipient, any use, dissemination, distribution or copying of the communication is strictly prohibited. If received in error, we apologize and ask that you please notify the Sender by returning this e-mail and permanently deleting this communication from your computer, including destruction of any printed copies. Any views expressed herein are not necessarily those of the Company represented by this e-mail source. No contracts, agreements or legally binding understandings may be entered into solely by an e-mail communication



epa rereg dci pbo with august 2 11 EPA letter comments 811.doc



epa rereg dci pbo with august 2 11 EPA letter comments clean 811.doc

# REGULATORY LABEL DATA SHEET

File Name: 796 rereg dcj pbo with august 2 11 EPA letter comments 811 Data Sheet Date: August 2011

Product: RF2042 [CDSO] EPA Reg #: 2724- 796

Approved: Amendment submitted 8/09 Supersedes:

OVERVIEW: Revised label for reregistration DCI, with August 2, 2011 EPA letter comments

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Page #	Description of Major Changes
1	Marketing claims: per August 2, 2011 EPA letter, #2 – added “and puppies” to second statement Net contents: add non-metric (US) measurements
2-3	per August 2, 2011 EPA letter, #3, Moved and reworded 4 statements to DFU Directions for Use: Use restrictions: per August 2, 2011 EPA letter, #4 – revised per letter and boxed Directions for Use: per August 2, 2011 EPA letter, #1 – deleted #5 in directions (addressed in Use Restrictions)
4	Storage/Disposal: per August 2, 2011 EPA letter, #5 – revised Pesticide Storage per comment per August 2, 2011 EPA letter, #7 – added “Container” to header Precautionary Statements: per August 2, 2011 EPA letter, #8 – revised “DO NOT USE ON” statement per August 2, 2011 EPA letter, #9 – added “hands” to sentence First Aid: per August 2, 2011 EPA letter, #10 – revised per comment

## RF2042 [CDSO]

For Toy [6-12 lbs.], Small [13-31 lbs.], Medium [32-55 lbs.], Large [56-80 lbs.], and Extra Large [81 lbs. and over] Dogs

[Flea & Tick [ & Mosquito][Treatment] [and] Control for Dogs and Puppies [6 months of age or older]]

Effective on indoor and outdoor dogs

[(1)[3][4][6] monthly treatments] [1][3][4][6] Months Supply [24][48] doses

Each tube [applicator] [kills fleas & ticks for 3 weeks] and [kills and repels mosquitoes for 3 to 4 weeks]

[Protects for up to [Four/4] Weeks][One month][Four/4 Week [Flea][Tick][Mosquito] Treatment]

[Aids in Control of Ticks for up to 30 days]

Contains an Insect Growth Regulator (IGR) to kill flea eggs and prevent flea development for [more than 10 weeks] up to [75 days][2.5 months]

[Starts Killing Fleas and Ticks within 15 minutes]

[Kills 85% of ticks within 48 hours][Kills more than 50% of fleas in 2 hours]

[Dual Action kills adult fleas and prevents flea development]

[Breaks Flea Life Cycle for [more than 10 weeks] up to [75 days][2.5 months]

[Controls flea reinfestation for [more than 10 weeks] up to [75 days][2.5 months]

[Kills fleas, ticks, mosquitoes, flea eggs and flea larvae] [Dual protection [against fleas and ticks]]

Kills the Deer Tick, which may transmit Lyme Disease

Kills and Repels mosquitoes (a major carrier of canine heartworm)

[With [S-Methoprene] Insect Growth Regulator [IGR] to Break Flea Life Cycle]

Convenient, easy to use ACCU-TIP DISPENSER [applicator][tube]

Spreads naturally with dog's movement [skin and hair oils]

[Formula][Contains lanolin for coat conditioning]

[Water Resistant] [to keep killing fleas and ticks in humid and wet conditions]

[Fast Acting][Long Lasting][Kills Fleas and Ticks by Contact]

[Easy to use] Longer applicator tip for easy application to long-haired dogs

[Fresh][Clean][Scent][Smell]

[Reapply monthly] [Suitable for year-round use][Month] sticker for home calendar

[Satisfaction guaranteed or your money back]

Alternate Applicator claims: Unique applicator [tube] with flow control

[no drip][no mess][application][applicator][tube]

(Front or Back panel)

### ACTIVE INGREDIENTS:

Etofenprox (CAS # 80844-07-1) ..... 30.0%

S-Methoprene (CAS # 65733-16-6) ..... 3.6%

Piperonyl Butoxide (CAS # 51-03-6)\* ..... 5.0%

OTHER INGREDIENTS: ..... 61.4%

TOTAL ..... 100.0%

\*(butyl carbityl) (6-propylpiperonyl ether) and related compounds

### KEEP OUT OF REACH OF CHILDREN

#### CAUTION

See Back Panel for [Ingredients and] Additional Precautionary Statements

NET CONTENTS: One: 0.05 fl.oz. (1.5 cc) Applicator [tube] [Toy Dogs]/0.10 fl.oz. (3.0 cc) Applicator [tube]  
[Small Dogs]/0.15 fl.oz. (4.5 cc) Applicator [tube] [Medium Dogs]/0.20 fl.oz. (6.0 cc)  
Applicator [tube] [Large Dogs]/0.30 fl.oz. (9.0 cc) Applicator [tube] [Extra Large Dogs]/

EPA Reg. No. 2724-796

EPA Est. No.

## RF2042 [CDSO]

**IMPORTANT!** Intended for Use on Dogs 6 Months of Age or Older

**READ ENTIRE LABEL BEFORE EACH USE. USE ONLY ON DOGS. DO NOT USE ON OTHER ANIMALS!**

[RF2042 [CDSO] prevents flea eggs from developing into adult fleas [more than 10 weeks] for up to [75 days][2.5 months]. RF2042 [CDSO] also kills fleas and ticks for 3 weeks and kills and repels mosquitoes for 3 to 4 weeks.]

**DIRECTIONS FOR USE:** It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

**IMPORTANT! READ ENTIRE LABEL BEFORE EACH USE. USE ONLY ON DOGS OR PUPPIES (6 MONTHS OF AGE OR OLDER). DO NOT USE ON OTHER ANIMALS!**

### USE RESTRICTIONS:

For indoor use only.

Do not apply this product to puppies less than 6 months of age.

Do not reapply this product for 30 days unless retreatment is required, but not sooner than 8 days after the initial treatment. Do not retreat more than 1 time per month.

The maximum application rate for this product is twice per month, and the second application must be made more than 8 days after the initial application.

RF2042 [CDSO] works by application directly to the dog's skin, not to the hair. When applying, manually push aside dog's hair to allow direct application to the skin. Do not get this product in dog's eyes or mouth.

[(Note: Application now assumes one applicator per animal per application)]

[Note: Each package contains sufficient tubes/applicators for [X] applications]

### FOR [TOY][SMALL] SIZE DOGS

1. Bend at perforation and tear off first applicator [tube]. [
2. Hold applicator [tube][and bend area of plastic at perforation, tear off and discard.] Hold applicator [tube] upright and snap tip back, away from face and body.
3. The dog should be standing for easy application. RF2042 [CDSO] should be applied evenly to [two spots][toy dogs][three spots][small dogs] on the top of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the tube on the skin and gently squeeze to expel a portion of the solution on the skin. Do not apply an excessive amount of the solution at any one spot that could cause some of the solution to run off the side of the dog.
4. Do not spread RF2042 [CDSO] by hand over the dog. Although the dog's skin and hair oils will naturally distribute the application over the entire dog, brushing the dog 12-24 hours after application will help to distribute the material over the skin..
5. Do not reapply product for 30 days unless re-treatment is required, but not sooner than 8 days after the initial treatment. Do not retreat more than once per month..
- 6.5. Discard empty [tube][applicator] as described in Storage and Disposal

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[Note: Each package contains sufficient tubes/applicators for [X] applications]

**FOR [MEDIUM][LARGE][EXTRA LARGE] DOGS**

- 1 Bend at perforation and tear off first applicator [tube]. [[Note – multi-application pack]]
- 2 Hold applicator [tube] and bend area of plastic at perforation, tear off and discard. Hold applicator [tube] upright and snap tip back, away from face and body
- 3 The dog should be standing for easy application. Apply RF2042 [CDSO] evenly to four or five spots on the top of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the tube on the skin and gently squeeze to expel a portion of the solution on the skin. Do not apply an excessive amount of the solution at any one spot that could cause some of the solution to run off the side of the dog.

**[Alternate Directions for Use for multi-tube application]**

- 3 The dog should be standing for easy application. Using the first applicator [tube], apply RF2042 [CDSO] evenly to four or five spots on the top of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the applicator [tube] on the skin and gently squeeze to expel a portion of the solution on the skin. Do not apply an excessive amount of the solution at any one spot that could cause some of the solution to run off the side of the dog. Using the second applicator [tube], apply as indicated for first applicator [tube] except start application at base of tail and apply on top of the back to the shoulder.
- 4 Do not spread RF2042 [CDSO] by hand over the dog. Although the dog's skin and hair oils will naturally distribute the application over the entire dog, brushing the dog 12-24 hours after application will help to distribute the material over the skin..
- 5 ~~Do not reapply product for 30 days unless re-treatment is required, but not sooner than 8 days after the initial treatment. Do not retreat more than once per month.~~
- 65 Discard empty [tube][applicator] as described in Storage and Disposal

RF2042 [CDSO] is most effective when used as part of a total flea and tick management program. Use other [Brand Name] products registered for residential area control of these pests in conjunction with this treatment. Monthly treatments are required for optimal control and prevention of fleas.

[The successive feeding activity of fleas on pets may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). Treatment of pets with RF2042 [CDSO] rapidly kills fleas and may reduce the incidence of this condition.]

[RF2042 [CDSO] is water resistant and remains efficacious following exposure to rainfall or swimming.]

TREATMENT SCHEDULE			
Dosage: 1 applicator every 30 days per dog			
Pet's Name	First Treatment Date	Second Treatment Date (30 Days From 1 <sup>st</sup> )	Third Treatment Date (30 Days From 2 <sup>nd</sup> )

Reminder: I purchased RF2042 [CDSO] from: \_\_\_\_\_

NOTES: \_\_\_\_\_

Treatment table can be expanded based on package size. (6 months)

**STORAGE and DISPOSAL:** **Pesticide Storage:** Keep this product in its tightly closed original container, when not in use. Store in a cool, dry (preferably locked) area that is inaccessible to away from children and animals. **Container Disposal:** If empty: Do not reuse container [tube][applicator]. Place in trash or offer for recycling if available. If partially filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

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#### PRECAUTIONARY STATEMENTS

##### HAZARDS TO HUMANS AND DOMESTIC ANIMALS - CAUTION

**DO NOT USE ON DOGS-PUPPIES LESS THAN 6 MONTHS OF AGE OR LESS.** For external use only. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Repeated exposure to etofenprox can cause skin irritation. Consult a veterinarian before using this product on debilitated, aged, pregnant, nursing, or animals on medication. Sensitivities may occur after using **ANY** pesticide product for pets. If signs of sensitivity occur, bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.

#### FIRST AID

If in eyes	<ul style="list-style-type: none"><li>• Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li><li>• Remove contact lenses, if present, after first 5 minutes, then continue rinsing</li><li>• Call a poison control center or doctor for treatment advice.</li></ul>
------------	--

Have the product container or label with you when calling a poison control center or doctor or going for treatment. For additional information on this pesticide product (including health concerns, medical emergencies or pesticide incidents), you may call also contact 1-800-XXX-XXXX, 24 hrs/day, 7 days/wk for emergency medical treatment information.

#### WARRANTY AND CONDITIONS OF SALE:

Seller warrants that this product conforms to the chemical specifications expressed on the label. To the extent consistent with applicable law, Seller makes no other warranties, and disclaims all other warranties, express or implied, including but not limited to warranties of merchantability and fitness for the intended purpose. To the extent consistent with applicable law, seller's liability for default, breach, or failure under this label shall be limited to the amount of the purchase price. To the extent consistent with applicable law, Seller shall have no liability for consequential damages.

In case of emergency or for product information, call 1-800-xxx-xxxx.

Wellmark International  
1501 E. Woodfield Road, 200W  
Schaumburg, Illinois 60173

[URL]

Made in USA

## RF2042 [CDSO]

For Toy (6-12 lbs.), Small (13-31 lbs.), Medium (32-55 lbs.), Large (56-80 lbs.), and Extra Large (81 lbs. and over) Dogs

[Flea & Tick [ & Mosquito][Treatment] [and] Control for Dogs and Puppies (6 months of age or older)]

Effective on indoor and outdoor dogs

[(1)[3]]4[(6) monthly treatments) [(1)[3][4][6) Months Supply [24][48] doses

Each tube [applicator] [kills fleas & ticks for 3 weeks] and [kills and repels mosquitoes for 3 to 4 weeks]

]Protects for up to [Four/4] Weeks]]One month]]Four/4 Week [Flea]]Tick]]Mosquito] Treatment]

]Aids in Control of Ticks for up to 30 days]

Contains an Insect Growth Regulator (IGR) to kill flea eggs and prevent flea development for [more than 10 weeks] up to [75 days][2.5 months]

[Starts Killing Fleas and Ticks within 15 minutes]

]Kills 85% of ticks within 48 hours][Kills more than 50% of fleas in 2 hours]

[Dual Action kills adult fleas and prevents flea development]

[Breaks Flea Life Cycle for [more than 10 weeks] up to [75 days][2.5 months]

[Controls flea reinfestation for [more than 10 weeks] up to [75 days][2.5 months]

[Kills fleas, ticks, mosquitoes, flea eggs and flea larvae] [Dual protection (against fleas and ticks)]

Kills the Deer Tick, which may transmit Lyme Disease

Kills and Repels mosquitoes (a major carrier of canine heartworm)

[With [S-Methoprene] Insect Growth Regulator [IGR] to Break Flea Life Cycle]

Convenient, easy to use ACCU-TIP DISPENSER [applicator][tube]

Spreads naturally with dog's movement (skin and hair oils)

[Formula]]Contains lanolin for coat conditioning]

[Water Resistant] ]to keep killing fleas and ticks in humid and wet conditions]

[Fast Acting][Long Lasting]]Kills Fleas and Ticks by Contact]

]Easy to use] Longer applicator tip for easy application to long-haired dogs

[Fresh][Clean][Scent][Smell]

[Reapply monthly] [Suitable for year-round use]]Month] sticker for home calendar

[Satisfaction guaranteed or your money back]

Alternate Applicator claims: Unique applicator [tube] with flow control

[no drip][no mess][application]]applicator][tube]

(Front or Back panel)

### ACTIVE INGREDIENTS:

Etofenprox (CAS # 80844-07-1) ..... 30.0%

S-Methoprene (CAS # 65733-16-6) ..... 3.6%

Piperonyl Butoxide (CAS # 51-03-6)\* ..... 5.0%

OTHER INGREDIENTS: ..... 61.4%

TOTAL ..... 100.0%

\*(butyl carbityl) (6-propylpiperonyl ether) and related compounds

### KEEP OUT OF REACH OF CHILDREN

#### CAUTION

See Back Panel for [Ingredients and] Additional Precautionary Statements

**NET CONTENTS:** One: 0.05 fl oz (1.5 cc) Applicator [tube] (Toy Dogs)/0.10 fl oz (3.0 cc) Applicator [tube] (Small Dogs)/0.15 fl oz (4.5 cc) Applicator [tube] (Medium Dogs)/0.20 fl oz (6.0 cc) Applicator [tube] (Large Dogs)/0.30 fl oz (9.0 cc) Applicator [tube] (Extra Large Dogs)/

EPA Reg. No. 2724-796

EPA Est. No.



[RF2042 [CDSO] prevents flea eggs from developing into adult fleas [more than 10 weeks] for up to [75 days][2.5 months]. RF2042 [CDSO] also kills fleas and ticks for 3 weeks and kills and repels mosquitoes for 3 to 4 weeks.]

**DIRECTIONS FOR USE:** It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

**IMPORTANT! READ ENTIRE LABEL BEFORE EACH USE. USE ONLY ON DOGS OR PUPPIES (6 MONTHS OF AGE OR OLDER). DO NOT USE ON OTHER ANIMALS!**

**USE RESTRICTIONS:**

For indoor use only.

Do not apply this product to puppies less than 6 months of age.

Do not reapply this product for 30 days unless retreatment is required, but not sooner than 8 days after the initial treatment. Do not retreat more than 1 time per month.

RF2042 [CDSO] works by application directly to the dog's skin, not to the hair. When applying, manually push aside dog's hair to allow direct application to the skin. Do not get this product in dog's eyes or mouth.

[(Note: Application now assumes one applicator per animal per application)]

[Note: Each package contains sufficient tubes/applicators for [X] applications]

**FOR [TOY][SMALL] SIZE DOGS**

1. Bend at perforation and tear off first applicator [tube]. [
2. Hold applicator [tube][and bend area of plastic at perforation, tear off and discard.] Hold applicator [tube] upright and snap tip back, away from face and body.
3. The dog should be standing for easy application. RF2042 [CDSO] should be applied evenly to [two spots](toy dogs)[three spots](small dogs) on the top of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the tube on the skin and gently squeeze to expel a portion of the solution on the skin. Do not apply an excessive amount of the solution at any one spot that could cause some of the solution to run off the side of the dog.
4. Do not spread RF2042 [CDSO] by hand over the dog. Although the dog's skin and hair oils will naturally distribute the application over the entire dog, brushing the dog 12-24 hours after application will help to distribute the material over the skin..
5. Discard empty [tube][applicator] as described in **Storage and Disposal**

[Note: Each package contains sufficient tubes/applicators for [X] applications]

**FOR [MEDIUM][LARGE][EXTRA LARGE] DOGS**

1. Bend at perforation and tear off first applicator [tube]. [(Note – multi-application pack)]
2. Hold applicator [tube][and bend area of plastic at perforation, tear off and discard.] Hold applicator [tube] upright and snap tip back, away from face and body
3. The dog should be standing for easy application. Apply RF2042 [CDSO] evenly to four or five spots on the top of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the tube on the skin and gently squeeze to expel a portion of the solution on the skin. Do not apply an excessive amount of the solution at any one spot that could cause some of the solution to run off the side of the dog.

### [Alternate Directions for Use for multi-tube application

- 3 The dog should be standing for easy application. Using the first applicator [tube], apply RF2042 [CDSO] evenly to four or five spots on the top of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the applicator [tube] on the skin and gently squeeze to expel a portion of the solution on the skin. Do not apply an excessive amount of the solution at any one spot that could cause some of the solution to run off the side of the dog. Using the second applicator [tube], apply as indicated for first applicator [tube] except start application at base of tail and apply on top of the back to the shoulder.
- 4 Do not spread RF2042 [CDSO] by hand over the dog. Although the dog's skin and hair oils will naturally distribute the application over the entire dog, brushing the dog 12-24 hours after application will help to distribute the material over the skin..
- 5 Discard empty [tube][applicator] as described in Storage and Disposal

RF2042 [CDSO] is most effective when used as part of a total flea and tick management program. Use other [Brand Name ] products registered for residential area control of these pests in conjunction with this treatment. Monthly treatments are required for optimal control and prevention of fleas.

[The successive feeding activity of fleas on pets may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). Treatment of pets with RF2042 [CDSO] rapidly kills fleas and may reduce the incidence of this condition.]

[RF2042 [CDSO] is water resistant and remains efficacious following exposure to rainfall or swimming.]

TREATMENT SCHEDULE			
Dosage: 1 applicator every 30 days per dog			
Pet's Name	First Treatment Date	Second Treatment Date (30 Days From 1 <sup>st</sup> )	Third Treatment Date (30 Days From 2 <sup>nd</sup> )

Reminder: I purchased RF2042 [CDSO] from: \_\_\_\_\_

NOTES: \_\_\_\_\_

Treatment table can be expanded based on package size. (6 months)

**STORAGE and DISPOSAL:** . **Pesticide Storage:** Keep this product in its tightly closed original container, when not in use. Store in a cool, dry (preferably locked) area that is inaccessible to children and animals. **Container Disposal:** If empty: Do not reuse container [tube][applicator]. Place in trash or offer for recycling if available. If partially filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

### PRECAUTIONARY STATEMENTS

#### HAZARDS TO HUMANS AND DOMESTIC ANIMALS - CAUTION

**DO NOT USE ON PUPPIES LESS THAN 6 MONTHS OF AGE.** For external use only. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Repeated exposure to etofenprox can cause skin irritation. Consult a veterinarian before using this product on debilitated, aged, pregnant, nursing, or animals on medication. Sensitivities may occur after using ANY pesticide product for pets. If signs of sensitivity occur, bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.

<b>FIRST AID</b>	
If in eyes	<ul style="list-style-type: none"> <li>• Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>• Remove contact lenses, if present, after first 5 minutes, then continue rinsing</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
Have the product container or label with you when calling a poison control center or doctor or going for treatment. For additional information on this pesticide product (including health concerns, medical emergencies or pesticide incidents), you may call 1-800-XXX-XXXX, 24 hrs/day, 7 days/wk.	

#### **WARRANTY AND CONDITIONS OF SALE:**

Seller warrants that this product conforms to the chemical specifications expressed on the label. To the extent consistent with applicable law, Seller makes no other warranties, and disclaims all other warranties, express or implied, including but not limited to warranties of merchantability and fitness for the intended purpose. To the extent consistent with applicable law, seller's liability for default, breach, or failure under this label shall be limited to the amount of the purchase price. To the extent consistent with applicable law, Seller shall have no liability for consequential damages.

In case of emergency or for product information, call 1-800-xxx-xxxx.

Wellmark International  
1501 E. Woodfield Road, 200W  
Schaumburg, Illinois 60173

**[URL]**

Made in USA



**Pre-Reregistration Labeling Review for EPA Reg. No. 2724-796 (RF2042 [CDSO])**

Carmen Rodia to: James McFadden  
Cc: Richard Gebken, Linda Arrington  
Bcc: Carmen Rodia

08/02/2011 02:51 PM

James, attached is an e-copy of a letter (a pre-reregistration label review) and a marked up copy of the reregistration label submitted in support of EPA Reg. No. 2724-796 (RF2042 [CDSO]). Within 10 working days, you must submit an updated reregistration label which incorporates all of the mitigation language required by the REDs for etofenprox, s-methoprene, and PBO. If you have any questions, please call me directly. Once the label has been updated, please e-mail it to me for future use in completing the reregistration for this product. Regards, Carmen Rodia.



2724-296 (RF2042 [CDSO]), Pre-reregistration Label Review (with provisions) (08-02-t1).pdf

Carmen J. Rodia, Jr.  
Environmental Protection Specialist  
U.S. EPA, Office of Pesticide Programs,  
Office of Chemical Safety and Pollution Prevention,  
Registration Division, Insecticide Branch  
1200 Pennsylvania Avenue, N.W. (7504P)  
Washington, DC 20460-0001  
(703) 306-0327 (tel)  
(703) 308-0029 (fax)  
Rodia.Carmen@epa.gov

Deliveries: One Potomac Yard (South Building)  
2777 South Crystal Drive  
Arlington, VA 22202-4501



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460-0001

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

Tuesday, August 2, 2011

**SENT VIA E-MAIL**

Mr. James McFadden, Ph.D.,  
Senior Regulatory Project Manager  
Wellmark International  
1501 East Woodfield Road, Suite 200 West  
Schaumburg, IL 60173-5417

**Subject: Request for Updated Reregistration Label for RF2042 [CDSO]  
EPA Registration No. 2724-796**

Dear Mr. McFadden:

The Agency, in accordance with the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, has completed reviewing all of the information submitted with your application to support the reregistration of the referenced product in connection with the REDs for **Etofenprox, S-Methoprene, and Piperonyl Butoxide**. Please make the following changes to the subject label:

General Comment(s):

1. Delete all text marked with "~~striketrough~~."

Optional Marketing Statements section comment(s):

2. Revise the 2<sup>nd</sup> optional marketing statement to read "[Flea & Tick [& Mosquito]][Treatment]][and]][Control for Dogs and Puppies (6 Months of Age or Older)]"

Directions for Use section comment(s):

3. Insert the revised/relocated statements "**IMPORTANT! READ ENTIRE LABEL BEFORE EACH USE. USE ONLY ON DOGS OR PUPPIES (6 MONTHS OF AGE OR OLDER). DO NOT USE ON OTHER ANIMALS!**" to appear on the subject label immediately following the statement "It is a violation of ..."
4. For consistency throughout the subject label, revise the "**USE RESTRICTIONS**" subsection to read as follows:

**USE RESTRICTIONS**

- For indoor use only.
- Do not apply this product to puppies less than 6 months of age.
- Do not reapply this product for 30 days unless re-treatment is required, but not sooner than 8 days after the initial treatment. Do not retreat more than 1 time per month.

Storage & Disposal section comment(s):

5. Revise the "**Pesticide Storage:**" subsection to read "Keep this product in its tightly closed original container, when not in use. Store in a cool, dry (preferably locked) area that is inaccessible to children and animals."
6. Insert the following new subsection immediately following the revised "**Pesticide Storage:**" subsection:  
"**Pesticide Disposal:** Wastes resulting from use of this product may be disposed of on site or at an approved waste disposal facility."
7. Revise the subsection heading "**Disposal:**" to read "**Container Disposal:**"

Precautionary Statements, Hazards to Humans and Domestic Animals subsection comment(s):

8. Revise the statement "**DO NOT USE ON DOGS 6 MONTHS OF AGE OR LESS.**" to read "**DO NOT USE ON PUPPIES LESS THAN 6 MONTHS OF AGE.**"
9. To incorporate required label changes from the acute toxicology review completed in support of this product, revise the 4<sup>th</sup> sentence within this subsection to read "Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet."

First Aid section comment(s):

10. Revise the 2<sup>nd</sup> sentence within the "**HOT LINE NUMBER:**" subsection to read "For additional information on this pesticide product (including health concerns, medical emergencies or pesticide incidents), you may call 1-800-xxx-xxxx, twenty-four (24) hours per day, seven (7) days per week."<sup>1</sup>

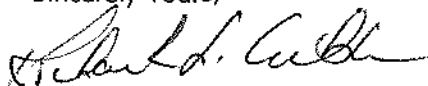
Should you wish to add/retain a reference to the company's website on your label, please be aware that the website becomes labeling under FIFRA and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under section 12(a)(1)(E) of FIFRA. 40 CFR §156.10(a)(5) lists examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not be substantially differ from those claims approved through the registration process. Therefore, should the Agency find, or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA-approved registration, the website will be referred to EPA's Office of Enforcement and Compliance Assurance (OECA). As an alternative, you may refer consumers to the company's phone number or e-mail address.

Within 10 working days of the date of this letter, you must submit an updated reregistration label incorporating all mitigation language required by the **REDs for Etofenprox, S-Methoprene, and Piperonyl Butoxide**. If we do not receive an updated label in response to this letter, the Agency may pursue further regulatory action, including cancellation in accordance with section 6(e) of FIFRA.

**PLEASE NOTE:** This product is not being reregistered under sections 3(c)5 and 4(g) of FIFRA at this time.

If you have any questions about this letter, please contact Mr. Carmen J. Rodia, Jr. at (703) 306-0327 or via e-mail at [Rodia.Carmen@epa.gov](mailto:Rodia.Carmen@epa.gov) or Mr. Richard J. Gebken at (703) 305-6701 or via e-mail at [Gebken.Richard@epa.gov](mailto:Gebken.Richard@epa.gov) during the hours of 9:00 A.M. to 5:30 P.M. EST.

Sincerely Yours,



Richard J. Gebken  
Product Manager (10)  
Insecticide Branch  
Registration Division (7504P)

Attachment: Copy of Marked-Up Label  
002724-00796 D450419

<sup>1</sup> Please note that the "1-800-xxx-xxxx" must be substituted with a valid phone number that is available twenty-four (24) hours per day, seven (7) days per week for answering and responding to any medical emergencies or health concerns.

## RF2042 [CDSO]

For Toy (6-12 lbs.), Small (13-31 lbs.), Medium (32-55 lbs.), Large (56-80 lbs.), and Extra Large (81 lbs. and over) Dogs

[Flea & Tick [& Mosquito][Treatment] [and] Control for Dogs 6 months of age or older]

Effective on indoor and outdoor dogs

[(1)[3][4][6] monthly treatments) [1][3][4][6] Months Supply [24][48] doses

Each tube [applicator] [kills fleas & ticks for 3 weeks] and [kills and repels mosquitoes for 3 to 4 weeks]

[Protects for up to [Four/4] Weeks][One month][Four/4 Week [Flea][Tick][Mosquito] Treatment]

[Aids in Control of Ticks for up to 30 days]

Contains an Insect Growth Regulator (IGR) to kill flea eggs and prevent flea development for

[more than 10 weeks] up to [75 days][2.5 months]

[Starts Killing Fleas and Ticks within 15 minutes]

[Kills 85% of ticks within 48 hours][Kills more than 50% of fleas in 2 hours]

[Dual Action kills adult fleas and prevents flea development]

[Breaks Flea Life Cycle for [more than 10 weeks] up to [75 days][2.5 months]

[Controls flea reinfestation for [more than 10 weeks] up to [75 days][2.5 months]

[Kills fleas, ticks, mosquitoes, flea eggs and flea larvae] [Dual protection (against fleas and ticks)]

Kills the Deer Tick, which may transmit Lyme Disease

Kills and Repels mosquitoes (a major carrier of canine heartworm)

[With [S-Methoprene] Insect Growth Regulator [IGR] to Break Flea Life Cycle]

Convenient, easy to use ACCU-TIP DISPENSER [applicator][tube]

Spreads naturally with dog's movement (skin and hair oils)

[Formula][Contains lanolin for coat conditioning]

[Water Resistant] [to keep killing fleas and ticks in humid and wet conditions]

[Fast Acting][Long Lasting][Kills Fleas and Ticks by Contact]

[Easy to use] Longer applicator tip for easy application to long-haired dogs

[Fresh][Clean][[Scent][Smell]

[Reapply monthly] [Suitable for year-round use][Month] sticker for home calendar

[Satisfaction guaranteed or your money back]

Alternate Applicator claims: Unique applicator [tube] with flow control

[no drip][no mess][application][applicator][tube]

(Front or Back panel)

### ACTIVE INGREDIENTS:

Etofenprox (CAS # 80844-07-1) ..... 30.0%

S-Methoprene (CAS # 65733-16-6) ..... 3.6%

Piperonyl Butoxide (CAS # 51-03-6)\* ..... 5.0%

OTHER INGREDIENTS: ..... 61.4%

TOTAL ..... 100.0%

\*(butyl carbityl) (6-propylpiperonyl ether) and related compounds

### KEEP OUT OF REACH OF CHILDREN

#### CAUTION

See Back Panel for [Ingredients and] Additional Precautionary Statements

NET CONTENTS: One: 1.5 cc Applicator [tube] (Toy Dogs)/3.0 cc Applicator [tube] (Small Dogs)/  
4.5 cc Applicator [tube] (Medium Dogs)/6.0 cc Applicator [tube] (Large Dogs)/  
9.0 cc Applicator [tube] (Extra Large Dogs)/

EPA Reg. No. 2724-796

EPA Est. No.

## ~~RF2042 [CDSO]~~

~~IMPORTANT! Intended for Use on Dogs 6 Months of Age or Older.~~

~~READ ENTIRE LABEL BEFORE EACH USE. USE ONLY ON DOGS. DO NOT USE ON OTHER ANIMALS.~~

[RF2042 [CDSO] prevents flea eggs from developing into adult fleas [more than 10 weeks] for up to [75 days][2.5 months]. RF2042 [CDSO] also kills fleas and ticks for 3 weeks and kills and repels mosquitoes for 3 to 4 weeks.]

**DIRECTIONS FOR USE:** It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

### **USE RESTRICTIONS:**

The maximum application rate for this product is twice per month, and the second application must be made more than 8 days after the initial application.

RF2042 [CDSO] works by application directly to the dog's skin, not to the hair. When applying, manually push aside dog's hair to allow direct application to the skin. Do not get this product in dog's eyes or mouth.

[(Note: Application now assumes one applicator per animal per application)]

[Note: Each package contains sufficient tubes/applicators for [X] applications]

#### **FOR [TOY][SMALL] SIZE DOGS**

1. Bend at perforation and tear off first applicator [tube]. [
2. Hold applicator [tube][and bend area of plastic at perforation, tear off and discard.] Hold applicator [tube] upright and snap tip back, away from face and body.
3. The dog should be standing for easy application. RF2042 [CDSO] should be applied evenly to [two spots][toy dogs][three spots][small dogs] on the top of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the tube on the skin and gently squeeze to expel a portion of the solution on the skin. Do not apply an excessive amount of the solution at any one spot that could cause some of the solution to run off the side of the dog.
4. Do not spread RF2042 [CDSO] by hand over the dog. Although the dog's skin and hair oils will naturally distribute the application over the entire dog, brushing the dog 12-24 hours after application will help to distribute the material over the skin..

~~Do not apply product for 20 days unless re-treatment is required, but not sooner than 8 days after the initial treatment. Do not retreat more than once per month.~~

6. Discard empty [tube][applicator] as described in Storage and Disposal

[Note: Each package contains sufficient tubes/applicators for [X] applications]

#### **FOR [MEDIUM][LARGE][EXTRA LARGE] DOGS**

1. Bend at perforation and tear off first applicator [tube]. [(Note – multi-application pack)]
2. Hold applicator [tube][and bend area of plastic at perforation, tear off and discard.] Hold applicator [tube] upright and snap tip back, away from face and body
3. The dog should be standing for easy application. Apply RF2042 [CDSO] evenly to four or five spots on the top of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the tube on the skin and gently squeeze to expel a portion of the solution on the skin. Do not apply an excessive amount of the solution at any one spot that could cause some of the solution to run off the side of the dog.



**[Alternate Directions for Use for multi-tube application]**

- 3 The dog should be standing for easy application. Using the first applicator [tube], apply RF2042 [CDSO] evenly to four or five spots on the top of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the applicator [tube] on the skin and gently squeeze to expel a portion of the solution on the skin. Do not apply an excessive amount of the solution at any one spot that could cause some of the solution to run off the side of the dog. Using the second applicator [tube], apply as indicated for first applicator [tube] except start application at base of tail and apply on top of the back to the shoulder.
- 4 Do not spread RF2042 [CDSO] by hand over the dog. Although the dog's skin and hair oils will naturally distribute the application over the entire dog, brushing the dog 12-24 hours after application will help to distribute the material over the skin..
- ~~5 Do not apply product for 30 days unless re-treatment is required, but not more than 3 days after the initial treatment. Do not retreat more than once per month.~~
- 6 Discard empty [tube][applicator] as described in Storage and Disposal

RF2042 [CDSO] is most effective when used as part of a total flea and tick management program. Use other [Brand Name ] products registered for residential area control of these pests in conjunction with this treatment. Monthly treatments are required for optimal control and prevention of fleas.

[The successive feeding activity of fleas on pets may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). Treatment of pets with RF2042 [CDSO] rapidly kills fleas and may reduce the incidence of this condition.]

[RF2042 [CDSO] is water resistant and remains efficacious following exposure to rainfall or swimming.]

TREATMENT SCHEDULE			
Dosage: 1 applicator every 30 days per dog			
Pet's Name	First Treatment Date	Second Treatment Date (30 Days From 1 <sup>st</sup> )	Third Treatment Date (30 Days From 2 <sup>nd</sup> )

Reminder: I purchased RF2042 [CDSO] from: \_\_\_\_\_

NOTES: \_\_\_\_\_

Treatment table can be expanded based on package size. (6 months)

**STORAGE and DISPOSAL:** . **Pesticide Storage:** Store in a cool area away from children and animals. **Disposal:** If empty: Do not reuse container [tube][applicator]. Place in trash or offer for recycling if available. If **partially filled:** Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

**PRECAUTIONARY STATEMENTS**

**HAZARDS TO HUMANS AND DOMESTIC ANIMALS - CAUTION**

**DO NOT USE ON DOGS 6 MONTHS OF AGE OR LESS.** For external use only. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Repeated exposure to etofenprox can cause skin irritation. Consult a veterinarian before using this product on debilitated, aged, pregnant, nursing, or animals on medication. Sensitivities may occur after using ANY pesticide product for pets. If signs of sensitivity occur, bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.

<b>FIRST AID</b>	
If in eyes	<ul style="list-style-type: none"> <li>• Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>• Remove contact lenses, if present, after first 5 minutes, then continue rinsing</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-XXX-XXXX for emergency medical treatment information.	

**WARRANTY AND CONDITIONS OF SALE:**

Seller warrants that this product conforms to the chemical specifications expressed on the label. To the extent consistent with applicable law, Seller makes no other warranties, and disclaims all other warranties, express or implied, including but not limited to warranties of merchantability and fitness for the intended purpose. To the extent consistent with applicable law, seller's liability for default, breach, or failure under this label shall be limited to the amount of the purchase price. To the extent consistent with applicable law, Seller shall have no liability for consequential damages.

In case of emergency or for product information, call 1-800-xxx-xxxx.

Wellmark International  
1501 E. Woodfield Road. 200W  
Schaumburg, Illinois 60173  
[URL]  
Made in USA

\*Confidential Statement of Formula may be entitled to confidential treatment\*

# DATA PACKAGE BEAN SHEET

Date: 23-Nov-2010

Page 1 of 2

Decision #: 410828

DP #: (384300)

NON PRIA

Parent DP #:

Submission #: 874998

## \*\*\* Registration Information \*\*\*

Registration: 2724-796 - RF 2042 (CDSO)

Company: 2724 - WELLMARK INTERNATIONAL

Risk Manager: RM 13 - Mark Suarez - (703) 305-0120 Room# PY1 S-7246

Risk Manager Reviewer: Julia Stokes JSTOKES4

Sent Date: 19-May-2010

Calculated Due Date: 10-May-2010

Edited Due Date:

Type of Registration: Product Registration - Section 3

Action Desc: (676) Product Reregistration Decision;

Ingredients: See page 2

## \*\*\* Data Package Information \*\*\*

Expedite: ☐ Yes ☒ No

Date Sent: 23-Nov-2010

Due Back:

DP Ingredient: See page 2

DP Title: PBO product 2724-796 for FINAL REVIEW in RD

CSF Included: ☒ Yes ☐ No

Label Included: ☒ Yes ☐ No

Parent DP #:

Assigned To

Date In

Date Out

Organization: RD / IB

Last Possible Science Due Date:

Team Name: RM 13

Science Due Date:

Reviewer Name:

Sub Data Package Due Date:

Contractor Name:

## \*\*\* Studies Sent for Review \*\*\*

No Studies

## \*\*\* Additional Data Package for this Decision \*\*\*

Can be printed on its own page

## \*\*\* Data Package Instructions \*\*\*

Mark,  
Please accept this PBO product 2724-796 for final Review in RD.  
This product under PBO has cited a CAS which was sent to JOe Diggs on 4-28-10  
D377134.

Thanks Julia

DP#: (384300)

\*\*\* Prod. and Data Package Ingredients \*\*\*

Decision#: (410828)

PC Code	CAS	Ingredient Name
067501	51-03-6	Piperonyl butoxide
105402	65733-16-6	S-Methoprene
128965	80844-07-1	Ethofenprox
067501	51-03-6	Piperonyl butoxide(5%)
105402	65733-16-6	S-Methoprene(3.6%)
128965	80844-07-1	Ethofenprox(30%)

Date: November 10, 2010

Reg. No.: 2724-796

Product Name: RF2042 [CDSO]

PM Name/Number: Mark Suarez, Risk Management Team 13

Primary Reviewer: Judy Loranger

Secondary Reviewer: Mark Perry

*Judy Loranger 11/22/10*  
*MTP*

New label or date of RD amended label: New, Received on 4/5/10

Active Ingredient(s) Assessed: Piperonyl butoxide/067501

Formulation Type: Liquid

Other ai's in product

Name/PC code:

S-Methoprene/105402

Ethofenprox/128965

Reregistration Status or Registration Date:

RED issued in 1991.

Registered after 1984.

Assessment can be found N:\RMIBV\label\002724/796

---

1) The registrant should be reminded that a telephone number for emergency medical treatment information should be added to the label.

**REGULATORY LABEL DATA SHEET****T**

**File Name:** 796 pbo dci 210.doc **Data Sheet Date:** February 2010  
**Product:** RF2042 [CDSO] **EPA Reg #:** 2724- 796  
**Approved:** Amendment submitted **Supersedes:**  
8/09

**OVERVIEW:** Revised label for reregistration DCI

Page #	Description of Major Changes
1	Ingredient Statement: Per DCI, revised PBO asterisked statement
2	Directions for Use: Added Use Restrictions per DCI

## RF2042 [CDSO]

For Toy (6-12 lbs.), Small (13-31 lbs.), Medium (32-55 lbs.), Large (56-80 lbs.), and Extra Large (81 lbs. and over) Dogs

[Flea & Tick [& Mosquito][Treatment] [and] Control for Dogs 6 months of age or older]

Effective on indoor and outdoor dogs

([1][3][4][6] monthly treatments) [1][3][4][6] Months Supply [24][48] doses

Each tube [applicator] [kills fleas & ticks for 3 weeks] and [kills and repels mosquitoes for 3 to 4 weeks]

[Protects for up to [Four/4] Weeks][One month][Four/4 Week [Flea][Tick][Mosquito] Treatment]

[Aids in Control of Ticks for up to 30 days]

Contains an Insect Growth Regulator (IGR) to kill flea eggs and prevent flea development for [more than 10 weeks] up to [75 days][2.5 months]

[Starts Killing Fleas and Ticks within 15 minutes]

[Kills 85% of ticks within 48 hours][Kills more than 50% of fleas in 2 hours]

[Dual Action kills adult fleas and prevents flea development]

[Breaks Flea Life Cycle for [more than 10 weeks] up to [75 days][2.5 months]

[Controls flea reinfestation for [more than 10 weeks] up to [75 days][2.5 months]

[Kills fleas, ticks, mosquitoes, flea eggs and flea larvae] [Dual protection (against fleas and ticks)]

Kills the Deer Tick, which may transmit Lyme Disease

Kills and Repels mosquitoes (a major carrier of canine heartworm)

[With [S-Methoprene] Insect Growth Regulator [IGR] to Break Flea Life Cycle]

Convenient, easy to use ACCU-TIP DISPENSER [applicator][tube]

Spreads naturally with dog's movement (skin and hair oils)

[Formula][Contains lanolin for coat conditioning]

[Water Resistant] [to keep killing fleas and ticks in humid and wet conditions]

[Fast Acting][Long Lasting][Kills Fleas and Ticks by Contact]

[Easy to use] Longer applicator tip for easy application to long-haired dogs

[Fresh][Clean][Scent][Smell]

[Reapply monthly] [Suitable for year-round use][Month] sticker for home calendar

[Satisfaction guaranteed or your money back]

Alternate Applicator claims: Unique applicator [tube] with flow control

[no drip][no mess][application][applicator][tube]

(Front or Back panel)

### ACTIVE INGREDIENTS:

Etofenprox (CAS # 80844-07-1) ..... 30.0%

S-Methoprene (CAS # 65733-16-6) ..... 3.6%

Piperonyl Butoxide (CAS # 51-03-6)\* ..... 5.0%

OTHER INGREDIENTS: ..... 61.4%

TOTAL ..... 100.0%

\*Equivalent to minimum 4.00%-(butyl carbityl) (6-propylpiperonyl ether) and 4.00%-related compounds

### KEEP OUT OF REACH OF CHILDREN

#### CAUTION

See Back Panel for [Ingredients and] Additional Precautionary Statements

NET CONTENTS: One: 1.5 cc Applicator [tube] (Toy Dogs)/3.0 cc Applicator [tube] (Small Dogs)/  
4.5 cc Applicator [tube] (Medium Dogs)/6.0 cc Applicator [tube] (Large Dogs)  
9.0 cc Applicator [tube] (Extra Large Dogs)

EPA Reg. No. 2724-796

EPA Est. No.



## **RF2042 [CDSO]**

**IMPORTANT! Intended for Use on Dogs 6 Months of Age or Older**

**READ ENTIRE LABEL BEFORE EACH USE. USE ONLY ON DOGS. DO NOT USE ON OTHER ANIMALS!**

[RF2042 [CDSO] prevents flea eggs from developing into adult fleas [more than 10 weeks] for up to [75 days][2.5 months]. RF2042 [CDSO] also kills fleas and ticks for 3 weeks and kills and repels mosquitoes for 3 to 4 weeks.]

**DIRECTIONS FOR USE:** It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

### **USE RESTRICTIONS:**

The maximum application rate for this product is twice per month, and the second application must be made more than 8 days after the initial application.

RF2042 [CDSO] works by application directly to the dog's skin, not to the hair. When applying, manually push aside dog's hair to allow direct application to the skin. Do not get this product in dog's eyes or mouth.

[(Note: Application now assumes one applicator per animal per application)]

[Note: Each package contains sufficient tubes/applicators for [X] applications]

### **FOR [TOY][SMALL] SIZE DOGS**

1. Bend at perforation and tear off first applicator [tube]. [
2. Hold applicator [tube][and bend area of plastic at perforation, tear off and discard.] Hold applicator [tube] upright and snap tip back, away from face and body.
3. The dog should be standing for easy application. RF2042 [CDSO] should be applied evenly to [two spots][toy dogs]three spots][small dogs) on the top of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the tube on the skin and gently squeeze to expel a portion of the solution on the skin. Do not apply an excessive amount of the solution at any one spot that could cause some of the solution to run off the side of the dog.
4. Do not spread RF2042 [CDSO] by hand over the dog. Although the dog's skin and hair oils will naturally distribute the application over the entire dog, brushing the dog 12-24 hours after application will help to distribute the material over the skin..
5. Do not reapply product for 30 days unless re-treatment is required, but not sooner than 8 days after the initial treatment. Do not retreat more than once per month..
6. Discard empty [tube][applicator] as described in Storage and Disposal

[Note: Each package contains sufficient tubes/applicators for [X] applications]

### **FOR [MEDIUM][LARGE][EXTRA LARGE] DOGS**

1. Bend at perforation and tear off first applicator [tube]. [(Note – multi-application pack)]
2. Hold applicator [tube][and bend area of plastic at perforation, tear off and discard.] Hold applicator [tube] upright and snap tip back, away from face and body
3. The dog should be standing for easy application. Apply RF2042 [CDSO] evenly to four or five spots on the top of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the tube on the skin and gently squeeze to expel a portion of the solution on the skin. Do not apply an excessive amount of the solution at any one spot that could cause some of the solution to run off the side of the dog.

### [Alternate Directions for Use for multi-tube application

- 3 The dog should be standing for easy application. Using the first applicator [tube], apply RF2042 [CDSO] evenly to four or five spots on the top of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the applicator [tube] on the skin and gently squeeze to expel a portion of the solution on the skin. Do not apply an excessive amount of the solution at any one spot that could cause some of the solution to run off the side of the dog. Using the second applicator [tube], apply as indicated for first applicator [tube] except start application at base of tail and apply on top of the back to the shoulder.
- 4 Do not spread RF2042 [CDSO] by hand over the dog. Although the dog's skin and hair oils will naturally distribute the application over the entire dog, brushing the dog 12-24 hours after application will help to distribute the material over the skin..
- 5 Do not reapply product for 30 days unless re-treatment is required, but not sooner than 8 days after the initial treatment. Do not retreat more than once per month.
- 6 Discard empty [tube][applicator] as described in Storage and Disposal

RF2042 [CDSO] is most effective when used as part of a total flea and tick management program. Use other [Brand Name ] products registered for residential area control of these pests in conjunction with this treatment. Monthly treatments are required for optimal control and prevention of fleas.

[The successive feeding activity of fleas on pets may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). Treatment of pets with RF2042 [CDSO] rapidly kills fleas and may reduce the incidence of this condition.]

[RF2042 [CDSO] is water resistant and remains efficacious following exposure to rainfall or swimming.]

TREATMENT SCHEDULE			
Dosage: 1 applicator every 30 days per dog			
Pet's Name	First Treatment Date	Second Treatment Date (30 Days From 1 <sup>st</sup> )	Third Treatment Date (30 Days From 2 <sup>nd</sup> )

Reminder: I purchased RF2042 [CDSO] from: \_\_\_\_\_

NOTES: \_\_\_\_\_

Treatment table can be expanded based on package size. (6 months)

**STORAGE and DISPOSAL:** . **Pesticide Storage:** Store in a cool area away from children and animals. **Disposal: If empty:** Do not reuse container [tube][applicator]. Place in trash or offer for recycling if available. **If partially filled:** Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

### PRECAUTIONARY STATEMENTS

#### HAZARDS TO HUMANS AND DOMESTIC ANIMALS - CAUTION

**DO NOT USE ON DOGS 6 MONTHS OF AGE OR LESS.** For external use only. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Repeated exposure to etofenprox can cause skin irritation. Consult a veterinarian before using this product on debilitated, aged, pregnant, nursing, or animals on medication. Sensitivities may occur after using ANY pesticide product for pets. If signs of sensitivity occur, bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.

<b>FIRST AID</b>	
If in eyes	<ul style="list-style-type: none"> <li>• Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>• Remove contact lenses, if present, after first 5 minutes, then continue rinsing</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-XXX-XXXX for emergency medical treatment information.	

**WARRANTY AND CONDITIONS OF SALE:**

Seller warrants that this product conforms to the chemical specifications expressed on the label. To the extent consistent with applicable law, Seller makes no other warranties, and disclaims all other warranties, express or implied, including but not limited to warranties of merchantability and fitness for the intended purpose. To the extent consistent with applicable law, seller's liability for default, breach, or failure under this label shall be limited to the amount of the purchase price. To the extent consistent with applicable law, Seller shall have no liability for consequential damages.

In case of emergency or for product information, call 1-800-xxx-xxxx.

Wellmark International  
1501 E. Woodfield Road. 200W  
Schaumburg, Illinois 60173  
[URL]  
Made in USA

# Material to be added to an e-Jacket/Jacket

Reg. No. 2724-796

Description: Product Reregistration (PRD)

1. ☐ Placement within the e-Jacket/jacket:
- ☐ Default: (chronological, top = newest)
  - ☐ File Location: (PDF page number, i.e., "before page 45")

2. ☐ Send to Data Extraction contractors this material:

- ☐ Newly stamped accepted label
- ☐ Notification
- ☐ New CSF
- ☐ Other: \_\_\_\_\_

3. Attach this coversheet to the top of the material or jacket. It must be well organized and clipped together, NOT STAPLED. Then give the material with this coversheet to staff in the Information Services Center (Room S-4900).

Reviewer's Name: Stokes

Phone: \_\_\_\_\_ Division: PRD

Date: 11/23/10

PRODUCT REREGISTRATION  
SUPPORTING DOCUMENTATION  
FOR

Case Name: PB0  
Reg. No. 2724-796

This supporting documentation (in chronological order) includes:

- ☐ Old labels (identified as "*Superceded by label dated xx/xx/xx*")
- ☐ Unacceptable CSF (marked "Not acceptable" and dated)
- ☒ Product chemistry reviews
- ☒ Acute toxicity reviews
- ☐ Efficacy and or special studies (if necessary)
- ☒ 90-Day responses to PDCI (forms A and B)
- ☒ Administrative forms (Application for Reregistration  
Certification to Data citation, Data Matrix)
- ☒ Correspondence (Company and Agency letters & e-mails)

Date: November 10, 2010

Reg. No.: 2724-796

Product Name: RF2042 [CDSO]

PM Name/Number: Mark Suarez, Risk Management Team 13

Primary Reviewer: Judy Loranger (Signed/JL/11/22/10)

Secondary Reviewer: Mark Perry (2<sup>nd</sup>/MP/11/22/10)

New label or date of RD amended label: New, Received on 4/5/10

Active Ingredient(s) Assessed: Piperonyl butoxide/067501

Formulation Type: Liquid

Other ai's in product

Name/PC code:

S-Methoprene/105402

Ethofenprox/128965

Reregistration Status or Registration Date:

RED issued in 1991.

Registered after 1984.

Assessment can be found N:\RMIBV\label\002724/796

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1) The registrant should be reminded that a telephone number for emergency medical treatment information should be added to the label.

rec'd 4-5-10

## RF2042 [CDSO]

For Toy (6-12 lbs.), Small (13-31 lbs.), Medium (32-55 lbs.), Large (56-80 lbs.), and Extra Large (81 lbs. and over) Dogs

[Flea & Tick [& Mosquito][Treatment] [and] Control for Dogs 6 months of age or older]

Effective on indoor and outdoor dogs

[(1)[3][4][6] monthly treatments) [1][3][4][6] Months Supply [24][48] doses

Each tube [applicator] [kills fleas & ticks for 3 weeks] and [kills and repels mosquitoes for 3 to 4 weeks]

[Protects for up to [Four/4] Weeks][One month][Four/4 Week [Flea][Tick][Mosquito] Treatment]

[Aids in Control of Ticks for up to 30 days]

Contains an Insect Growth Regulator (IGR) to kill flea eggs and prevent flea development for [more than 10 weeks] up to [75 days][2.5 months]

[Starts Killing Fleas and Ticks within 15 minutes]

[Kills 85% of ticks within 48 hours][Kills more than 50% of fleas in 2 hours]

[Dual Action kills adult fleas and prevents flea development]

[Breaks Flea Life Cycle for [more than 10 weeks] up to [75 days][2.5 months]

[Controls flea reinfestation for [more than 10 weeks] up to [75 days][2.5 months]

[Kills fleas, ticks, mosquitoes, flea eggs and flea larvae] [Dual protection [against fleas and ticks]]

Kills the Deer Tick, which may transmit Lyme Disease

Kills and Repels mosquitoes (a major carrier of canine heartworm)

[With [S-Methoprene] Insect Growth Regulator [IGR] to Break Flea Life Cycle]

Convenient, easy to use ACCU-TIP DISPENSER [applicator][tube]

Spreads naturally with dog's movement (skin and hair oils)

[Formula][Contains lanolin for coat conditioning]

[Water Resistant] [to keep killing fleas and ticks in humid and wet conditions]

[Fast Acting][Long Lasting][Kills Fleas and Ticks by Contact]

[Easy to use] [Longer applicator tip for easy application to long-haired dogs]

[Fresh][Clean][Scent][Smell]

[Reapply monthly] [Suitable for year-round use][Month] sticker for home calendar

[Satisfaction guaranteed or your money back]

Alternate Applicator claims: Unique applicator [tube] with flow control

[no drip][no mess][application][applicator][tube]

(Front or Back panel)

### ACTIVE INGREDIENTS:

Etofenprox (CAS # 80844-07-1) ..... 30.0%

S-Methoprene (CAS # 65733-16-6)..... 3.6%

Piperonyl Butoxide (CAS # 51-03-6)\* ..... 5.0%

OTHER INGREDIENTS: ..... 61.4%

TOTAL ..... 100.0%

\*(butyl carbityl) (6-propylpiperonyl ether) and related compounds

### KEEP OUT OF REACH OF CHILDREN

#### CAUTION

See Back Panel for [Ingredients and] Additional Precautionary Statements

#### NET CONTENTS:

One: 1.5 cc Applicator [tube] (Toy Dogs)/3.0 cc Applicator [tube] (Small Dogs)/  
4.5 cc Applicator [tube] (Medium Dogs)/6.0 cc Applicator [tube] (Large Dogs)/  
9.0 cc Applicator [tube] (Extra Large Dogs)/

EPA Reg. No. 2724-796

EPA Est. No.

## **RF2042 [CDSO]**

**IMPORTANT! Intended for Use on Dogs 6 Months of Age or Older**

**READ ENTIRE LABEL BEFORE EACH USE. USE ONLY ON DOGS. DO NOT USE ON OTHER ANIMALS!**

[RF2042 [CDSO] prevents flea eggs from developing into adult fleas [more than 10 weeks] for up to [75 days][2.5 months]. RF2042 [CDSO] also kills fleas and ticks for 3 weeks and kills and repels mosquitoes for 3 to 4 weeks.]

**DIRECTIONS FOR USE:** It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

### **USE RESTRICTIONS:**

The maximum application rate for this product is twice per month, and the second application must be made more than 8 days after the initial application.

RF2042 [CDSO] works by application directly to the dog's skin, not to the hair. When applying, manually push aside dog's hair to allow direct application to the skin. Do not get this product in dog's eyes or mouth.

[(Note: Application now assumes one applicator per animal per application)]

[Note: Each package contains sufficient tubes/applicators for [X] applications]

### **FOR [TOY][SMALL] SIZE DOGS**

1. Bend at perforation and tear off first applicator [tube]. [
2. Hold applicator [tube][and bend area of plastic at perforation, tear off and discard.] Hold applicator [tube] upright and snap tip back, away from face and body.
3. The dog should be standing for easy application. RF2042 [CDSO] should be applied evenly to [two spots](toy dogs)[three spots](small dogs) on the top of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the tube on the skin and gently squeeze to expel a portion of the solution on the skin. Do not apply an excessive amount of the solution at any one spot that could cause some of the solution to run off the side of the dog.
4. Do not spread RF2042 [CDSO] by hand over the dog. Although the dog's skin and hair oils will naturally distribute the application over the entire dog, brushing the dog 12-24 hours after application will help to distribute the material over the skin..
5. Do not reapply product for 30 days unless re-treatment is required, but not sooner than 8 days after the initial treatment. Do not retreat more than once per month..
6. Discard empty [tube][applicator] as described in Storage and Disposal

[Note: Each package contains sufficient tubes/applicators for [X] applications]

### **FOR [MEDIUM][LARGE][EXTRA LARGE] DOGS**

1. Bend at perforation and tear off first applicator [tube]. [(Note – multi-application pack)]
2. Hold applicator [tube][and bend area of plastic at perforation, tear off and discard.] Hold applicator [tube] upright and snap tip back, away from face and body
3. The dog should be standing for easy application. Apply RF2042 [CDSO] evenly to four or five spots on the top of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the tube on the skin and gently squeeze to expel a portion of the solution on the skin. Do not apply an excessive amount of the solution at any one spot that could cause some of the solution to run off the side of the dog.



**[Alternate Directions for Use for multi-tube application]**

- 3 The dog should be standing for easy application. Using the first applicator [tube], apply RF2042 [CDSO] evenly to four or five spots on the top of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the applicator [tube] on the skin and gently squeeze to expel a portion of the solution on the skin. Do not apply an excessive amount of the solution at any one spot that could cause some of the solution to run off the side of the dog. Using the second applicator [tube], apply as indicated for first applicator [tube] except start application at base of tail and apply on top of the back to the shoulder.
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RF2042 [CDSO] is most effective when used as part of a total flea and tick management program. Use other [Brand Name ] products registered for residential area control of these pests in conjunction with this treatment. Monthly treatments are required for optimal control and prevention of fleas.

[The successive feeding activity of fleas on pets may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). Treatment of pets with RF2042 [CDSO] rapidly kills fleas and may reduce the incidence of this condition.]

[RF2042 [CDSO] is water resistant and remains efficacious following exposure to rainfall or swimming.]

TREATMENT SCHEDULE			
Dosage: 1 applicator every 30 days per dog			
Pet's Name	First Treatment Date	Second Treatment Date (30 Days From 1 <sup>st</sup> )	Third Treatment Date (30 Days From 2 <sup>nd</sup> )

Reminder: I purchased RF2042 [CDSO] from: \_\_\_\_\_

NOTES: \_\_\_\_\_

Treatment table can be expanded based on package size. (6 months)

**STORAGE and DISPOSAL:** . **Pesticide Storage:** Store in a cool area away from children and animals. **Disposal:** If empty: Do not reuse container [tube][applicator]. Place in trash or offer for recycling if available. If partially filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

**PRECAUTIONARY STATEMENTS****HAZARDS TO HUMANS AND DOMESTIC ANIMALS - CAUTION**

**DO NOT USE ON DOGS 6 MONTHS OF AGE OR LESS.** For external use only. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Repeated exposure to etofenprox can cause skin irritation. Consult a veterinarian before using this product on debilitated, aged, pregnant, nursing, or animals on medication. Sensitivities may occur after using ANY pesticide product for pets. If signs of sensitivity occur, bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.

<b>FIRST AID</b>	
If in eyes	<ul style="list-style-type: none"> <li>• Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>• Remove contact lenses, if present, after first 5 minutes, then continue rinsing</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-XXX-XXXX for emergency medical treatment information.	

#### **WARRANTY AND CONDITIONS OF SALE:**

Seller warrants that this product conforms to the chemical specifications expressed on the label. To the extent consistent with applicable law, Seller makes no other warranties, and disclaims all other warranties, express or implied, including but not limited to warranties of merchantability and fitness for the intended purpose. To the extent consistent with applicable law, seller's liability for default, breach, or failure under this label shall be limited to the amount of the purchase price. To the extent consistent with applicable law, Seller shall have no liability for consequential damages.

In case of emergency or for product information, call 1-800-xxx-xxxx.

Wellmark International  
1501 E. Woodfield Road. 200W  
Schaumburg, Illinois 60173

**[URL]**

Made in USA



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

June 3, 2010

MEMORANDUM:

Subject: EPA Reg. No.: 2724-796 RF2042 [CDSO]  
DP Barcode: 377133  
Case No.: 2525

From: Jolene Trujillo, Biologist *Jolene E. Trujillo*  
Risk Management and Implementation Branch V (7508P)  
Pesticide Re-evaluation Division

To: Julia Stokes, CRM  
Risk Management and Implementation Branch V (7508P)  
Pesticide Re-evaluation Division

Applicant: Wellmark International  
1501 East Woodfield Road, Suite 200 West  
Schaumburg, IL 60173

*MJP*

FORMULATION FROM EPA Reg. No. 2724-796 LABEL:

	<u>% by wt.</u>
<u>Active Ingredient(s):</u>	
Etofenprox ...	30.00%
S-Methoprene.....	3.60%
Piperonyl Butoxide.....	5.00%
<u>Other Ingredients:</u> .....	<u>61.40%</u>
Total	100.00%

**BACKGROUND:** In the 8 month response to the Piperonyl Butoxide (PBO) RED, the registrant has submitted acute toxicity studies to support the reregistration of their product, EPA Reg. No. 2724-796. The MRID's are as follows: 475185-04 (81-1), 475185-05 (81-2), 475185-06 (81-4), 475185-07 (81-5), 475185-08 (81-6). All studies were conducted by Eurofins Product Safety Laboratories. The test material was the subject product. The registrant submitted a waiver for Acute Inhalation (81-3), MRID No. 475185-09. The studies and waiver were previously reviewed by TRB/RD on 02/04/09 and PRD/RMIBV agrees with the findings of those reviews.

**RECOMMENDATIONS:**

- The acute toxicity studies cited are acceptable to support the reregistration of EPA Reg. No. 2724-796.

The acute toxicity profile for EPA Reg. No. 2724-796 is currently:

Acute Oral	IV	Cited
Acute Dermal	IV	Cited
Acute Inhalation	IV	Waived
Primary Eye	III	Cited
Primary Dermal	IV	Cited
Skin Sensitization	Non-sensitizer	Cited

NOTE: The acute toxicity requirements have been satisfied for the subject product.

**LABELING:**

**ID#:** 2724-796 RF2042 [CDSO]

**SIGNAL WORD:** CAUTION

**HAZARDS TO HUMANS AND DOMESTIC ANIMALS:**

Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.

**FIRST AID:**

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

Have product container or label with you when calling a poison control center or doctor or going to treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

04/FEB/2009

**MEMORANDUM**

Subject: Name of Pesticide Product: RF2042[CDSO]  
EPA Reg. No. /File Symbol: 2724-TOA  
DP Barcode: D357271  
Decision No.: 399095  
PC Codes: 128965 (etofenprox)  
105402 (s-methoprene)  
067501 (piperonyl butoxide)

From: Eugenia McAndrew, Biologist  
Technical Review Branch  
Registration Division (7505P)

*E. McAndrew*

*M. Haslam  
(T. J. Fennell)*

To: Kevin Sweeney, RM Team 13  
Insecticide Branch  
Registration Division (7505P)

Applicant: Wellmark International  
1501 East Woodfield Road, Suite 200 West  
Schaumburg, Illinois 60173

**FORMULATION FROM LABEL:**

<u>Active Ingredient(s):</u>	<u>% by wt</u>
Etofenprox	30.0
S-Methoprene	3.6
Piperonyl Butoxide	5.0
<u>Inert Ingredient(s):</u>	<u>61.4</u>
Total:	100.0%

**ACTION REQUESTED:** Risk Manager requests: Please review attached acute toxicity studies.  
Note that the registrant has requested a waiver from the acute inhalation study.

**BACKGROUND:** Wellmark International has submitted acute oral, acute dermal, primary eye irritation, primary skin irritation and dermal sensitization studies to support the registration of the proposed product, RF2042[CDSO], EPA File Symbol 2724-TOA. The studies were conducted at Product Safety Laboratories, Dayton, New Jersey with assigned MRID numbers 475185-04 to -08. A CSF for a basic formulation dated August 15, 2008 is included in the submission.

The registrant is requesting a waiver from the requirement for an acute inhalation toxicity study (MRID 47518509). The waiver request rationale is as follows:

- All of the active ingredients have been tested for acute inhalation toxicity and are classified as EPA Toxicity Category IV.
- The inert ingredients are on the EPA list or Inert Ingredients Permitted for Use in Non-Food Use Pesticide Products (January 7, 2008).
- The manner which the product will be applied and the physical properties of the formulation do not have potential to produce an inhalation hazard.
- The product is packaged in single use individual applicators with directions to "hold applicator upright and snap tip back, away from face and body."

**RECOMMENDATIONS:** The five studies have been reviewed and are classified as acceptable. TRB agrees with the request for a waiver of the acute inhalation toxicity study.

The acute toxicity profile for RF2042[CDSO], EPA File Symbol 2724-TOA, is as follows:

Acute oral toxicity	IV	Acceptable	MRID 47518504
Acute dermal toxicity	IV	Acceptable	MRID 47518505
Acute inhalation toxicity	IV	Waived	MRID 47518509
Primary eye irritation	III	Acceptable	MRID 47518506
Primary skin irritation	IV	Acceptable	MRID 47518507
Dermal sensitization	Negative	Acceptable	MRID 47518508

**LABELING:** Based on the toxicity profile above, the following are the precautionary and first aid statements for this product as obtained from the Label Review System:

**PRODUCT ID #:** 002724-00796

**PRODUCT NAME:** RF2042[CDSO]

**PRECAUTIONARY STATEMENTS**

**SIGNAL WORD:** CAUTION

**Hazards to Humans and Domestic Animals:**

Causes moderate eye irritation. Avoid contact with eyes or clothing. [Wear protective eyewear.]\* Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.

\*[Protective eyewear may be specified, if appropriate.]

**First Aid:**

If in eyes:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

**Reviewer:** Eugenia McAndrew  
**Risk Manager (EPA):** 13

**Date:** February 4, 2009

**STUDY TYPE:** Acute Oral Toxicity – Rat; OPPTS 870.1100; OECD 425

**TEST MATERIAL:** RF2042[CDSO](Lot # 495-97; 30.0% etofenprox, 3.60% methoprene and 5.00% piperonyl butoxide; oily yellowish liquid)

**CITATION:** Lowe, C. (2008) RF2042[CDSO – Acute Oral Toxicity Up and Down Procedure in Rats. Study Number 22373. Eurofins/Product Safety Laboratories, 2394 US Highway 130, Dayton, NJ 08810. March 20, 2008. MRID 47518504.

**SPONSOR:** Wellmark International. 1501 E. Woodfield Road, Suite 200W. Schaumburg, IL 60173

**EXECUTIVE SUMMARY:** In an acute oral toxicity study (MRID 47518504), three fasted, young adult female Sprague-Dawley rats (age: 9-10 weeks; body weight: 174-220 g; source: Ace Animals, Inc., Boyertown, PA) were given a single dose of RF2042[CDSO](Lot # 495-97; 30.0% etofenprox, 3.60% methoprene and 5.00% piperonyl butoxide; oily yellowish liquid) as received at a limit dose of 5000 mg/kg bw by gavage and observed for 14 days.

All animals survived, gained weight and appeared active and healthy throughout the study. No gross abnormalities were noted at necropsy.

LD<sub>50</sub> Females > 5000 mg/kg bw

**RF2042[CDSO] is in EPA Toxicity Category IV.**

This study is classified as acceptable. It does satisfy the guideline requirements for an acute oral study (OPPTS 870.1100; OECD 425) in the rat.

**COMPLIANCE:** Signed and dated GLP, Quality Assurance and Data Confidentiality statements were provided.



## RESULTS and DISCUSSION:

AOT425statpgm (Version: 1.0) Test Results and Recommendations  
Acute Oral Toxicity (OECD Test Guideline 425) Statistical Program

Date/Time: Wednesday, January 21, 2009, 11:50:18 AM

Data file name: work.dat

Last modified: 01/21/2009 11:50:16 AM

Test/Substance: RF2042[CDSO]

Test type: Limit Test

Limit dose (mg/kg): 5000

Assumed LD<sub>50</sub> (mg/kg): Default

Assumed sigma (mg/kg): 0.5

### DATA:

Test Seq.	Animal ID	Dose (mg/kg)	Short-term Result	Long-term Result
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1	3101	5000	O	O
2	3102	5000	O	O
3	3103	5000	O	O

(X = Died, O = Survived)

Dose Recommendation: The limit test is complete.

### SUMMARY OF LONG-TERM RESULTS:

Dose	O	X	Total
------	---	---	-------

5000	3	0	3
------	---	---	---

All Doses	3	0	3
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### Statistical Estimates:

The LD<sub>50</sub> is greater than 5000 mg/kg.

Animals were dosed as follows:

Animal Number	Sex	Dose Level (mg/kg)	Long-Term Outcome
3102	F	5000	S
3103	F	5000	S
3103	F	5000	S

S = Survival, D = Death

- A. **Mortality**: All animals survived the study.
- B. **Clinical observations**: All animals gained weight and appeared active and healthy throughout the study.
- C. **Gross necropsy**: No gross abnormalities were noted.
- D. **Reviewer's conclusions**: This reviewer agrees with the study author regarding the acute oral LD<sub>50</sub>.

**Reviewer:** Eugenia McAndrew  
**Risk Manager (EPA):** 13

**Date:** February 4, 2009

**STUDY TYPE:** Acute Dermal Toxicity – Rat; OPPTS 870.1200; OECD 402

**TEST MATERIAL:** RF2042[CDSO](Lot #.495-97; 30.0% etofenprox, 3.60% methoprene and 5.00% piperonyl butoxide; oily yellowish liquid)

**CITATION:** Lowe, C. (2008) RF2042[CDSO] – Acute Dermal Toxicity Study in Rats – Limit Test. Study Number 22374. Eurofins/Product Safety Laboratories, 2394 US Highway 130, Dayton, NJ 08810. March 20, 2008. MRID 47518505.

**SPONSOR:** Wellmark International. 1501 E. Woodfield Road, Suite 200W. Schaumburg, IL 60173

**EXECUTIVE SUMMARY:** In an acute dermal toxicity study (MRID 47518505), young adult Sprague-Dawley rats (5/sex; age: 8-9 weeks; body weight: males: 235-285 g and females: 168-195 g; source: Ace Animals, Inc., Boyertown, PA) were dermally exposed for 24 hours on an area of approximately 10% of the total body surface area on the clipped dorsal trunk to 5000 mg/kg bw RF2042[CDSO](Lot # 495-97; 30.0% etofenprox, 3.60% methoprene and 5.00% piperonyl butoxide; oily yellowish liquid) as received. The test material was applied evenly over the dose area and covered with a gauze pad. The gauze pad and the trunk were wrapped with Durapore tape. The animals were observed for 14 days.

All animals survived, and gained weight and appeared active and healthy throughout the study. Dermal irritation (erythema and/or edema) was noted at 3/10 dose sites on days 1-2. No gross abnormalities were noted at necropsy.

LD<sub>50</sub> Males > 5000 mg/kg bw  
LD<sub>50</sub> Females > 5000 mg/kg bw  
LD<sub>50</sub> Combined > 5000 mg/kg bw

**RF2042[CDSO] is in EPA Toxicity Category IV.**

This study is classified as acceptable. It does satisfy the guideline requirements for an acute dermal study (OPPTS 870.1200; OECD 402) in the rat.

**COMPLIANCE:** Signed and dated GLP, Quality Assurance and Data Confidentiality statements were provided.

**RESULTS and DISCUSSION:**

Dose (mg/kg bw)	Mortality/Number Tested		
	Males	Females	Combined
5000	0/5	0/5	0/10

A. **Mortality:** All animals survived the study.

B. **Clinical observations:** All animals gained weight and appeared active and healthy throughout the study. Dermal irritation (erythema and/or edema) was noted at 3/10 does sites on days 1-2.

C. **Gross necropsy:** No gross abnormalities were noted at necropsy.

D. **Reviewer's conclusions:** This reviewer agrees with the study author regarding the acute dermal LD<sub>50</sub>.

Reviewer: Eugenia McAndrew  
Risk Manager (EPA): 13

Date: February 4, 2009

**STUDY TYPE:** Primary Eye Irritation – Rabbit; OPPTS 870.2400; OECD 405

**TEST MATERIAL:** RF2042[CDSO](Lot # 495-97; 30.0% etofenprox, 3.60% methoprene and 5.00% piperonyl butoxide; oily yellowish liquid)

**CITATION:** Lowe, C. (2008) RF2042[CDSO] – Primary Eye Irritation Study in Rabbits. Study Number 22375. Eurofins/Product Safety Laboratories, 2394 US Highway 130, Dayton, NJ 08810. March 20, 2008. MRID 47518506.

**SPONSOR:** Wellmark International. 1501 E. Woodfield Road, Suite 200W, Schaumburg, IL 60173

**EXECUTIVE SUMMARY:** In a primary eye irritation study (MRID 47518506), 0.1 mL of undiluted RF2042[CDSO](Lot # 495-97; 30.0% etofenprox, 3.60% methoprene and 5.00% piperonyl butoxide; oily yellowish liquid) was instilled as received into the conjunctival sac of the right eye of three female young adult New Zealand albino rabbits (source: Robinson Services, Inc., Clemmons, NC). The untreated eye served as a control. Prior to instillation, 2 drops of ocular anesthetic (Tetraicaine Hydrochloride Ophthalmic Solution, 0.5%) were placed into both the treated and control eye of each animal. The animals were observed for 72 hours.

Iritis and positive conjunctival irritation were noted on 3/3 animals one hour after test material instillation. No positive scores were noted at 48 hours and all eyes were free of irritation by 72 hours.

**RF2042[CDSO] is classified as EPA Toxicity Category III for primary eye irritation.**

This study is classified as acceptable. It does satisfy the guideline requirements for a primary eye irritation study (OPPTS 870.2400; OECD 405) in the rabbit.

**COMPLIANCE:** Signed and dated GLP, Quality Assurance and Data Confidentiality statements were provided.

## RESULTS and DISCUSSION:

	Number "positive"/Number treated			
	Hours			
<b>Observations</b>	1	24	48	72
Corneal Opacity	0/3	0/3	0/3	0/3
Iritis	3/3	2/3	0/3	0/3
Conjunctivae:				
Redness*	3/3	0/3	0/3	0/3
Chemosis*	0/3	0/3	0/3	0/3
Discharge**	3/3	0/3	0/3	0/3

\* Score of 2 or more required to be considered "positive"

\*\* Discharge is not a positive effect according to the grading scale

- A. **Observations:** Iritis and positive conjunctival irritation were noted on 3/3 animals one hour after test material instillation. No positive scores were noted at 48 hours and all eyes were free of irritation by 72 hours.
- B. **Results:** RF2042[CDSO] was mildly irritating.
- C. **Reviewer's conclusions:** This reviewer agrees with the study author that the test material was mildly irritating and classified as EPA Toxicity Category III.

**Reviewer:** Eugenia McAndrew  
**Risk Manager (EPA):** 13

**Date:** February 4, 2009

**STUDY TYPE:** Primary Dermal Irritation – Rabbit; OPPTS 870.2500; OECD 404

**TEST MATERIAL:** RF2042[CDSO](Lot # 495-97; 30.0% etofenprox, 3.60% methoprene and 5.00% piperonyl butoxide; oily yellowish liquid)

**CITATION:** Lowe, C. (2008) RF2042[CDSO] – Primary Skin Irritation Study in Rabbits. Study Number 22376. Eurofins/Product Safety Laboratories, 2394 US Highway 130, Dayton, NJ 08810. March 20, 2008. MRID 47518507.

**SPONSOR:** Wellmark International. 1501 E. Woodfield Road, Suite 200W. Schaumburg, IL 60173

**EXECUTIVE SUMMARY:** In a primary dermal irritation study (MRID 47518507), three young adult female New Zealand albino rabbits (source: Robinson Services, Inc., Clemmons, NC) were dermally exposed to 0.5 mL of undiluted RF2042[CDSO](Lot # 495-97; 30.0% etofenprox, 3.60% methoprene and 5.00% piperonyl butoxide; oily yellowish liquid) for 4 hours on a 6 cm<sup>2</sup> area of the clipped dorsal skin that was covered with a gauze pad. The pad and trunk were wrapped with semi-occlusive Micropore tape. Elizabethan collars were placed on the rabbits. The animals were observed and irritation was scored at 1, 24, 48, and 72 hours after patch removal.

Very slight erythema was noted on 3/3 rabbits 30-60 minutes after patch removal. All sites were free of irritation by 24 hours.

**In this study, RF2042[CDSO] is classified as EPA Toxicity Category IV for primary dermal irritation.**

This study is classified as acceptable. It does satisfy the guideline requirements for a primary dermal irritation study (OPPTS 870.2500; OECD 404) in the rabbit.

**COMPLIANCE:** Signed and dated GLP, Quality Assurance and Data Confidentiality statements were provided.

**RESULTS and DISCUSSION:**

**Erythema/Edema**

Animal Number/Sex	Hours After Patch Removal				Days
	1	24	48	72	
3501/F	1/0	0/0	0/0	0/0	0/0
3502/F	1/0	0/0	0/0	0/0	0/0
3503/F	1/0	0/0	0/0	0/0	0/0

- A. **Observations:** Very slight erythema was noted on 3/3 rabbits 30-60 minutes after patch removal. All sites were free of irritation by 24 hours.
- B. **Results:** RF2042[CDSO] was slightly irritating. The Primary Irritation Index (PII) is 0.3.
- C. **Reviewer's conclusions:** This reviewer agrees with the study author that the test material was slightly irritating.



**Reviewer:** Eugenia McAndrew  
**Risk Manager (EPA):** 13

**Date:** February 4, 2009

**STUDY TYPE:** Dermal Sensitization -- guinea pig; OPPTS 870.2600; OECD 406

**TEST MATERIAL:** RF2042[CDSO](Lot # 495-97; 30.0% etofenprox, 3.60% methoprene and 5.00% piperonyl butoxide; oily yellowish liquid)

**CITATION:** Lowe, C. (2008) RF2042[CDSO – Dermal Sensitization Study in Guinea Pigs (Buehler Method). Study Number 22377. Eurofins/Product Safety Laboratories, 2394 US Highway 130, Dayton, NJ 08810. March 20, 2008. MRID 47518508.

**SPONSOR:** Wellmark International. 1501 E. Woodfield Road, Suite 200W. Schaumburg, IL 60173

**EXECUTIVE SUMMARY:** In a dermal sensitization study (MRID 47518508) with RF2042[CDSO](Lot # 495-97; 30.0% etofenprox, 3.60% methoprene and 5.00% piperonyl butoxide; oily yellowish liquid), 30 young adult Hartley albino guinea pigs (body weight: males: 356-423 g and females: 324-375 g; source: Elm Hill Breeding Labs, Chelmsford, MA) were tested using the Buehler Method. The test animals were induced with 0.4 mL of undiluted test material for six hours using occlusive 25 mm Hill Top Chambers that were secured and wrapped with non-allergenic adhesive tape. The procedure was repeated once each week for three consecutive weeks. Twenty-seven days after the first induction, the test animals were challenged with 0.4 mL of undiluted test material under occlusion to naive sites. The naive control animals were treated with 0.4 mL of undiluted test material under occlusion at challenge. Reactions were scored 24 and 48 hours after test material applications.

After three consecutive weekly inductions, no positive dermal reactions were noted from any animal after challenge.

**Based on the results of this study, RF2042[CDSO] was not a dermal sensitizer**

This study is classified as acceptable. It does satisfy the guideline requirements for a dermal sensitization study (OPPTS 870.2600; OECD 406) in the guinea pig.

**COMPLIANCE:** Signed and dated GLP, Quality Assurance and Data Confidentiality statements were provided.

## PROCEDURE:

- A. **Induction:** The animals were induced and challenged according to the Buehler method. The dorsal and flank areas of 20 test guinea pigs were clipped prior to each treatment. For induction, 0.4 mL of undiluted test material was applied to the animal using an occlusive 25 mm Hill Top Chamber and secured with non-allergenic adhesive tape. The chamber was removed after six hours and excess test material removed. The procedure was repeated once each week for three consecutive weeks. Reactions were scored 24 and 48 hours after the induction applications.
- B. **Challenge:** Twenty-seven days after the first induction, the test animals were challenged with 0.4 mL of undiluted test material under occlusion to naive sites for 6 hours. Reactions were scored 24 and 48 hours after challenge application.
- C. **Naive control:** The dorsal and flank areas of 10 naive control animals were clipped prior to treatment. At challenge, the naive control group was treated with 0.4 mL of undiluted test material for 6 hours. Reactions were scored 24 and 48 hours following challenge application.

## RESULTS and DISCUSSION:

- A. **Reactions and durations:** Very faint usually non-confluent erythema (0.5) was noted on 17/20 test animals over the course of three inductions. Very faint usually non-confluent erythema was noted on 11/20 test animals at 24 hours and on 4/20 test animals at 48 hours after challenge. Very faint usually non-confluent erythema was noted on 4/10 naive control animals 24 hours after challenge persisting at one site at 48 hours. The test material was not a dermal sensitizer.
- B. **Positive control:** The report included the results of a positive control (alpha-hexylcinnamaldehyde) study # 21953 conducted within six months of the current study; the results were appropriate.
- C. **Reviewer's conclusion:** This reviewer agrees with the study author that the test material was not a dermal sensitizer.

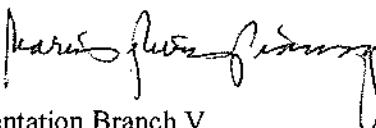
1. **DP BARCODE:** DP357271
2. **PC CODES:** 128965, 105402, 067501
3. **CURRENT DATE:** February 4, 2009
4. **TEST MATERIAL:** RF2042[CDSO](Lot # 495-97; 30.0% etofenprox, 3.60% methoprene and 5.00% piperonyl butoxide; oily yellowish liquid)

Study/Species/Lab Study # / Date	MRID	Results	Tox. Cat.	Core Grade
Acute oral toxicity/rat Eurofins/Product Safety Laboratories 22373/March 20, 2008	47518504	LD <sub>50</sub> > 5000 mg/kg bw females	IV	A
Acute dermal toxicity/rat Eurofins/Product Safety Laboratories 22374/March 20, 2008	47518505	LD <sub>50</sub> > 5000 mg/kg bw males, females combined	IV	A
Acute inhalation toxicity waiver request 3474/August 12, 2008	47518509	Waived	IV	W
Primary eye irritation/rabbit Eurofins/Product Safety Laboratories 22375/March 20, 2008	47518506	Mildly irritating	III	A
Primary dermal irritation/rabbit Eurofins/Product Safety Laboratories 22376/March 20, 2008	47518507	Slightly irritating	IV	A
Dermal sensitization/Guinea pig Eurofins/Product Safety Laboratories 22377/March 20, 2008	47518508	Not sensitizing	-	A

Core Grade Key: A = Acceptable, S = Supplementary, U = Unacceptable, W = Waived

DATE OUT: 03/NOV/2010

SUBJECT: PRODUCT CHEMISTRY REVIEW OF: TGAI [ ]; MUP [ ]; EUP [X]  
BARCODE NO.: D377132 REG./FILE SYMBOL NO.: 2724-796  
PRODUCT NAME: RF2042 [CDSO]  
MRID NOS.: 475185-01, -02, -03, 480782-01, 480890-01  
COMPANY NAME: Wellmark International ACTION CODE: 676  
CONTRACTOR: CSC PROJECT CODE: PRD-281 OPII

FROM: Maria Rivera Piansay, Chemist   
Product Chemistry Team  
Risk Management and Implementation Branch V  
Pesticide Re-evaluation Division (7508P)

TO: Julia Stokes, CRM  
Risk Management and Implementation Branch V  
Pesticide Re-evaluation Division (7508P)

### INTRODUCTION:

A Reregistration Eligibility Decision (RED), Case number 2525, was issued on June 14, 2006 for the Technical Grade Active Ingredient (TGAI) Piperonyl Butoxide (PBO). According to the RED, the generic data base supporting the reregistration of Piperonyl Butoxide for currently registered uses has been reviewed and found to be substantially complete. [Additional generic data are required to confirm the reregistration eligibility decision documented in the RED.]

In the 8-month response to the Piperonyl Butoxide (PBO) RED, Wellmark International provided a Response to the Data-Call In for PBO, 9/14/2009; a Confidential Statement of Formula (CSF) for the basic formulation, dated 8/15/2008; EPA Form 8570-35 (Data Matrix), dated 2/24/2010; a draft label (received 4/5/10); and two studies (MRID Nos. 480782-01, 480890-01) to supplement cited product chemistry data in MRID Nos. 475185-01, -02, and -03. The registrant is requesting reregistration of their product, RF2042 [CDSO], EPA Reg. No. 2724-796.

### FINDINGS:

1. EPA Reg. No. 2724-796 is an end-use insecticide, containing the active ingredients, Etofenprox, S-Methoprene, and PBO, with label claim nominal concentrations of 30.0%, 3.6%, and 5.0%, respectively. The product is an insecticide for use in controlling fleas, mosquitoes, and ticks on dogs. The product is produced by a non-integrated system.
2. The CSF for the basic formulation is acceptable. The nominal concentrations of the active ingredients agree with that on the draft label, meeting PR Notice 91-2. The certified limits for the active ingredients and inert ingredients are acceptable in accordance with 40 CFR §158.175(b)(2). All ingredients listed on the CSF are cleared for use in pesticide formulations.

THIS REVIEW CONTAINS FIFRA CBI

3. The data reported in MRID Nos. 475185-01, -02, -03, 480782-01 and 480890-01 satisfy the product chemistry requirements as specified in 40 CFR §158.155, 158.160, 158.165, 158.167, 158.175, and 158.180 (the new 40 CFR section numbers are 158.320, 158.325, 158.335, 158.340, 158.350, and 158.355, respectively) which pertain to Product Identity and Composition, Description of Materials Used to Produce the Product, Description of Formulation Process, Discussion of Formation of Impurities, Certified Limits, and Enforcement Analytical Method.

The data also satisfy the product chemistry requirements as specified in 40 CFR §158.190 (the new 40 CFR number is 158.310) which pertain to the Physical and Chemical properties of the product.

4. The Enforcement Analytical Method for the determination of active ingredient content in the product is presented in MRID No. 475185-03. The method is adequate and satisfies the requirements under Guideline 830.1800.
5. The Ingredients Statement on the draft label is acceptable as per 40 CFR §156.10(g) and PR Notices 91-2 and 97-6. No data are present to trigger the need for a Physical or Chemical Hazards Statement. The Storage and Disposal Statements are acceptable in accordance with 40 CFR §156.10(i)(2)(ix) and PR Notice 83-3. The following revision to the label is recommended: place the Storage and Disposal Statements in a text box for prominence.

NOTE TO CRM: The labeling issues should be addressed during label review.

#### **CONCLUSIONS:**

The registrant has satisfied the product chemistry requirements for the reregistration of EPA Reg. No. 2724-796.

**Product Chemistry Data****Subgroup A: Guidelines Series 830.1550 - 830.1800 (40 CFR §158.320 - 158.355)****Product Identity, Composition, and Analysis**

<b>Guideline Reference No. (GRN) / Title 830</b>	<b>40 CFR §</b>	<b>MRID Number</b>	<b>Data Fulfilled</b>
830.1550 Product Identity and Composition	158.320	475185-01, 480782-01 and CSF	Y
830.1600 Description of Materials Used to Produce the Product	158.325	475185-01, 480782-01 and CSF	Y
830.1620 Description of Production Process	158.330	<i>[Not required for products produced by a non-integrated system]</i>	NR
830.1650 Description of Formulation Process	158.335	475185-01, 480782-01 and CSF	Y
830.1670 Discussion of Formation of Impurities	158.340	475185-01, 480782-01	Y
830.1700 Preliminary Analysis	158.345	<i>[Not required for products produced by a non-integrated system]</i>	NR
830.1750 Certified Limits	158.350	475185-01 and CSF	Y
830.1800 Enforcement Analytical Method	158.355	475185-03	Y

**Subgroup B: Guideline Series 830.6302 - 830.7950 (40 CFR §158.310)****Physical and Chemical Properties**

<b>Guideline Reference No. (GRN) / Title 830</b>	<b>Value or Qualitative Description</b>	<b>MRID Number</b>	<b>Data Fulfilled</b>
.6302 Color	Pale yellow at 25±1°C, similar to Munsell Color 7.5Y 9/4	475185-02	Y
.6303 Physical State	Liquid, cloudy at 25±1°C	475185-02	Y
.6304 Odor	Weak, neutral, chemical like at 25±1°C	475185-02	Y

Guideline Reference No. (GRN) / Title 830	Value or Qualitative Description	MRID Number	Data Fulfilled																																																
.6314 Oxidation/ Reduction: Chemical Incompatibility	Not applicable. Product does not contain oxidizing or reducing agents.	Response to Data-Call In	N/A																																																
.6315 Flammability/Flame Extension	135.9°C (Pensky-Martens Closed Tester)	475185-02	Y																																																
.6316 Explodability	Not applicable. Product is not potentially explosive.	Response to Data-Call In	N/A																																																
.6317 Storage Stability	<table><tr><th colspan="2">Etofenprox</th></tr><tr><th>Time Point</th><th>Active Conc.*</th></tr><tr><td>Initial</td><td>30.32%</td></tr><tr><td>3 months</td><td>29.98%</td></tr><tr><td>6 months</td><td>30.59%</td></tr><tr><td>9 months</td><td>30.24%</td></tr><tr><td>12 months</td><td>30.24%</td></tr><tr><td>24 months</td><td>30.20%</td></tr></table> <p>*Mean concentration</p> <table><tr><th colspan="2">S-Methoprene</th></tr><tr><th>Time Point</th><th>Active Conc.*</th></tr><tr><td>Initial</td><td>3.63%</td></tr><tr><td>3 months</td><td>3.55%</td></tr><tr><td>6 months</td><td>3.62%</td></tr><tr><td>9 months</td><td>3.60%</td></tr><tr><td>12 months</td><td>3.58%</td></tr><tr><td>24 months</td><td>3.57%</td></tr></table> <p>*Mean concentration</p> <table><tr><th colspan="2">PBO</th></tr><tr><th>Time Point</th><th>Active Conc.*</th></tr><tr><td>Initial</td><td>4.56%</td></tr><tr><td>3 months</td><td>4.44%</td></tr><tr><td>6 months</td><td>4.55%</td></tr><tr><td>9 months</td><td>4.51%</td></tr><tr><td>12 months</td><td>4.49%</td></tr><tr><td>24 months</td><td>4.50%</td></tr></table> <p>*Mean concentration</p> <p>Results demonstrate</p>	Etofenprox		Time Point	Active Conc.*	Initial	30.32%	3 months	29.98%	6 months	30.59%	9 months	30.24%	12 months	30.24%	24 months	30.20%	S-Methoprene		Time Point	Active Conc.*	Initial	3.63%	3 months	3.55%	6 months	3.62%	9 months	3.60%	12 months	3.58%	24 months	3.57%	PBO		Time Point	Active Conc.*	Initial	4.56%	3 months	4.44%	6 months	4.55%	9 months	4.51%	12 months	4.49%	24 months	4.50%	480890-01	Y
Etofenprox																																																			
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24 months	4.50%																																																		

Guideline Reference No. (GRN) / Title 830	Value or Qualitative Description	MRID Number	Data Fulfilled
	stability for 24 months under warehouse conditions. No significant change in the concentrations of the active ingredients was observed over the 24-month interval. No changes in the color, odor, or physical state of the product were observed. The product was tested in its commercial style package (Barex/Barex) (3.0 cc container size).		
.6317 (continued)	Note: Results also demonstrate stability for 24 months under warehouse conditions, when the product was tested in 1.5 cc containers.	480890-01	Y
.6317 (continued)	Note: Results also demonstrate stability for 24 months at 40°C, when the product was tested in 3.0 cc containers.	480890-01	Y
.6317 (continued)	Note: Results also demonstrate stability for 24 months at 40°C, when the product was tested in 1.5 cc containers.	480890-01	Y
.6319 Miscibility	Not applicable. Product not to be diluted.	Response to Data-Call In	N/A



Guideline Reference No. (GRN) / Title 830	Value or Qualitative Description	MRID Number	Data Fulfilled
.6320 Corrosion Characteristics	Results demonstrate that the product is not corrosive to its packaging after storage for 24 months at warehouse conditions and at 40°C. Examination of the container found no cracking, leaking, discoloration, or other visible abnormalities that affected the product through 24 months of study. No failures of package closure or leaks were observed during conduct of the study. The package material is a Barex/Barex, thermoformed tray with a laminate foil lid stock attached to the back of the package.	480890-01	Y
.6321 Dielectric Breakdown Voltage	Not applicable. Product not applied near electrical equipment.	Response to Data-Call In	N/A
.7000 pH	Not applicable. Product not a water solution.	Response to Data-Call In	N/A
.7100 Viscosity	118.70 mPa·s at 20.0°C; and 25.19 mPa·s at 40.0°C; Newtonian fluid	475185-02	Y
.7300 Density/Relative Density	0.994 g/mL at 20°C	475185-02	Y

Explanations: Y = Requirement fulfilled; N = Requirement not fulfilled; N/A = Not applicable;  
G = Data gap; U = Upgradeable; I = Incomplete or in progress; W = Waived; NR = Not required

Enforcement Analytical Method, Guideline 830.1800 (MRID No. 475185-03)

A GC method with flame ionization detection is used to determine active ingredient content in the product ("Procedure for the Analysis of (S)-methoprene, butylcarbityl 6-propylpiperonyl ether (PBO), and etofenprox in Combi Cat and Dog spot-on products using Capillary Column Gas Chromatography with Flame Ionization Detection"). The method has been validated. The method provides procedures for preparing standards and samples, a description of the instrument system, and equations for calculations. This method is found to be adequate and would satisfy Guideline 830.1800.

The GC system consists of the following:

Instrument:	Agilent or (HP) 5890 or 6890 Gas Chromatograph with FID
Sampler:	Agilent or (HP) 7673 or 6890 Automatic Sampler
Data System:	Chromatography Data System
Column:	DB-1 (capillary) 30 m x 0.32 mm I.D., 0.25 µm film
Detector:	Flame Ionization
Linear Velocity:	Helium ~36 cm/sec at 220°C
Gas Flows:	
Helium	~30 mL/min (inake up)
Hydrogen	~40 mL/min
Air	~400 mL/min
Column Flow	~1.75 mL/min
Total Flow	~35 mL/min
Septum Purge	~1.50 mL/min
Carrier:	Helium
Injection Temp:	250°C
Detector Temp:	300°C
Injection Type:	Split 25:1
Volume:	1 µL
Oven Temp:	
Initial Value	180°C
Initial Time	11 min
Program Rate	40°C/min
Final Value	260°C
Final Time	8 min
Program Rate-A	60°C/min
Final Value-A	325°C
Final Time-A	7.92 min
Total Run Time	30 min
Equilibrium Time:	1.00 min

Confidential Appendix A830.1550 Product Identity and Composition

EPA Reg. No. 2724-796 is an end-use product produced by a non-integrated system. The product contains the active ingredients, Etofenprox, S-Methoprene, and PBO, with label claim nominal concentrations of 30.0%, 3.6%, and 5.0%, respectively. Sources of the active ingredients include the following registered products:

- 
- (S)-Methoprene Technical (EPA Reg. No. 2724-442; 94.0% active)

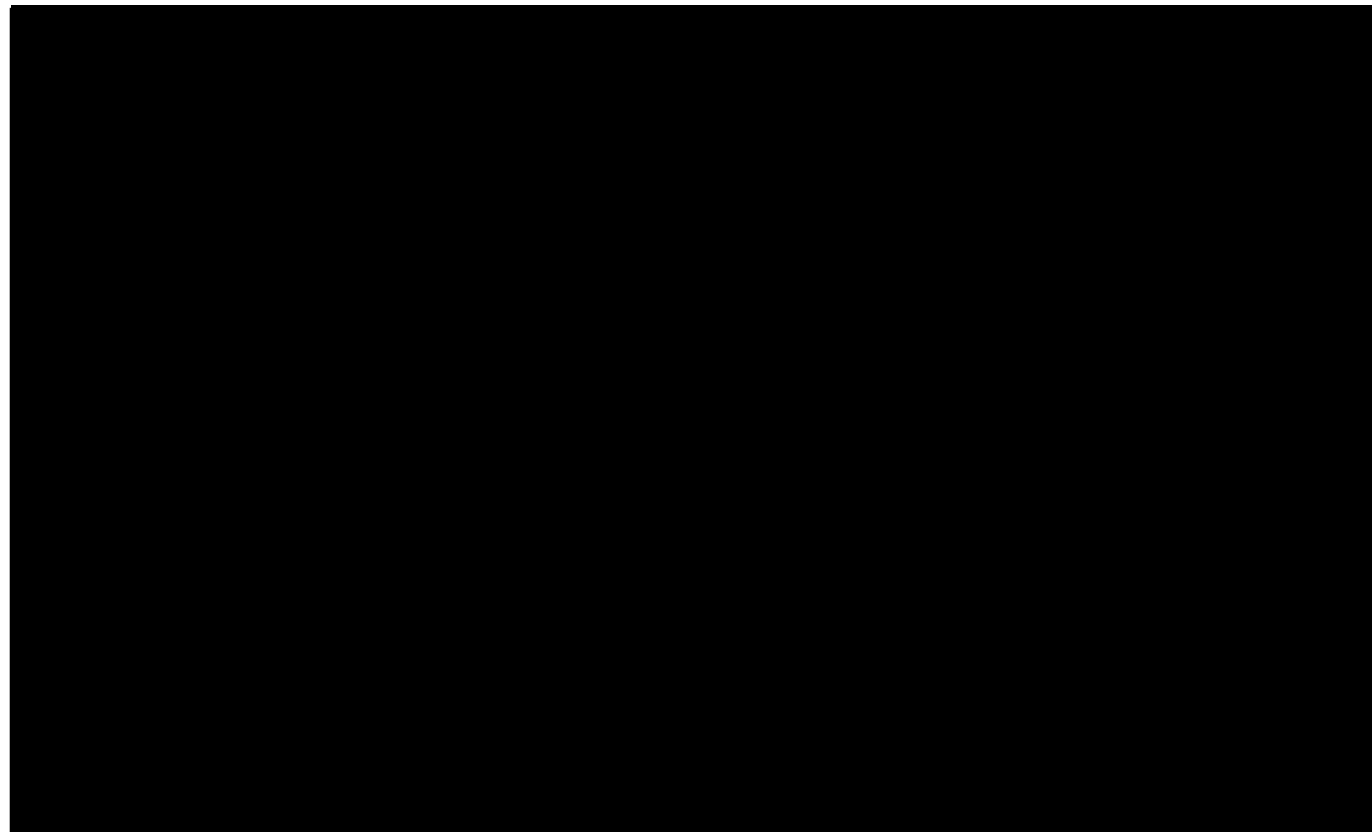
Nominal concentrations and upper/lower certified limits are identified in MRID No. 475185-01 and on the CSF.

830.1600 Description of Materials Used to Produce the Product

The starting materials used in the formulation of EPA Reg. No. 2724-796 are identified in MRID No. 475185-01 and on the CSF. Technical specifications were not provided; however, MSDSs were found to be available on the Internet for each inert formulation component.

830.1650 Description of Formulation Process

The formulation process is described in MRID No. 475185-01, as follows:



830.1670 Discussion of Formation of Impurities

A discussion of impurity formation is provided in MRID No. 475185-01. The product is produced in a formulation process and not as an integrated system. No known additional impurities are formed by the formulation processes that are not already present in the technical grades of the active ingredients or synergists.

830.1750 Certified Limits

The CSF for the basic formulation, dated 8/15/2008, provides the following certified limits for the active ingredient sources and active ingredients:

Component	Lower Certified Limit	Nominal Concentration	Upper Certified Limit
	% by weight		
Etofenprox source Etofenprox	(29.10)	(30.00)	(30.90)
S-Methoprene source S-Methoprene	3.64 (3.42)	3.83 (3.60)	4.02 (3.78)
PBO source PBO	(4.75)	(5.00)	(5.25)

THIS REVIEW CONTAINS FIFRA CBI



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
1200 Pennsylvania Avenue, N.W.  
WASHINGTON, D.C. 20460

Form Approved OMB Nos. 2070-0060; 2070-0057;  
2070-0107; 2070-0122; 2070-0164

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DATA MATRIX

Date: February 24, 2010		EPA Reg No./File Symbol	2724-796	Page 1 of 1	
Applicant's/Registrant's Name & Address		Product			
Wellmark International 1501 E. Woodfield Rd., Suite 200 West Schaumburg, IL 60173		RF2042 (CDSO)			
Ingredients: (S)-Methoprene, Etofenprox, PBO					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.1600 - 830.1750	Description of Materials and Formulation Process	47518501	Wellmark International	OWN	
830.6302 - 830.7300	Product Chemistry - Physical and Chemical Properties	47518502	Wellmark International	OWN	
830.6317, 830.6320	Storage Stability, Corrosion Characteristics	48089001	Wellmark International	OWN	To be submitted
830.1800	Enforcement Analytical Method	47518503	Wellmark International	OWN	
870.1100	Acute Oral Toxicity	47518504	Wellmark International	OWN	
870.1200	Acute Dermal Toxicity	47518505	Wellmark International	OWN	
870.1300	Acute Inhalation Toxicity	47518509	Wellmark International	OWN	
870.2400	Acute Eye Irritation	47518506	Wellmark International	OWN	
870.2500	Acute Dermal Irritation	47518507	Wellmark International	OWN	
870.2600	Dermal Sensitization	47518508	Wellmark International	OWN	
810.3300	Efficacy - Fleas and Ticks	47518511	Wellmark International	OWN	
810.3300	Efficacy - Fleas and Ticks	47518512, 47578402	Wellmark International	OWN	
810.3300	Efficacy - Fleas and Ticks	47844002	Wellmark International	OWN	
870.7200	Target Animal Safety	47844001	Wellmark International	OWN	
870.7200	Target Animal Safety - Puppies	47622203, 47835301, 47578401	Wellmark International	OWN	
870.7200	Target Animal Safety - Dogs	47518510	Wellmark International	OWN	
Signature			Name and Title		Date
			James McFadden, Regulatory Project Manager		February 24, 2010

EPA Form 8570-35 (12-2003) Electronic and Paper versions available. Submit only paper version.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
1200 Pennsylvania Avenue, N.W.  
WASHINGTON, D.C. 20460

Form Approved OMB Nos. 2070-0060; 2070-0057;  
2070-0107; 2070-0122; 2070-0164

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reviewing the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, Collection Strategies Division (2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: February 24, 2010		EPA Reg No./File Symbol 2724-796		Page 1 of 1	
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Wellmark International 1501 E. Woodfield Rd., Suite 200 West Schaumburg, IL 60173		RF2042 (CDSO)			
Ingredients: (S)-Methoprene, Etofenprox, PBO					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Wellmark International	OWN	
			Wellmark International	OWN	
			Wellmark International	OWN	To be submitted
			Wellmark International	OWN	
			Wellmark International	OWN	
			Wellmark International	OWN	
			Wellmark International	OWN	
			Wellmark International	OWN	
			Wellmark International	OWN	
			Wellmark International	OWN	
			Wellmark International	OWN	
			Wellmark International	OWN	
			Wellmark International	OWN	
			Wellmark International	OWN	
			Wellmark International	OWN	submitted 2/24/2010
			Wellmark International	OWN	
			Wellmark International	OWN	
			Wellmark International	OWN	
			Wellmark International	OWN	submitted 2/24/2010
			Signature		Name and Title
		James McFadden, Regulatory Project Manager		February 24, 2010	

**TRANSMITTAL DOCUMENT****1. NAME AND ADDRESS OF SUBMITTER**

Wellmark International  
1501 E. Woodfield Road  
Suite 200 West  
Schaumburg, IL 60173

**2. REGULATORY ACTION SUPPORTED BY THIS SUBMISSION**

Submission of Reports to Support Data Call-In Requirements for  
EPA Reg. No. 2724-796, RF2042 [CDSO]

**3. TRANSMITTAL DATE**

April 28, 2010

**4. LIST OF DOCUMENTS SUBMITTED**

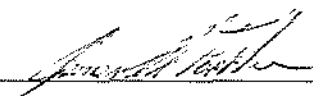
- 48078201** 1. McFadden, T. (2010) RF2042 [CDSO] Description of Materials and Formulation Process, unpublished, Wellmark International Study No. 3798, 10 pp.

**5. COMPANY NAME**

Wellmark International

**6. COMPANY AGENT**

James McFadden  
Regulatory Project Manager  
Wellmark International  
1501 E. Woodfield Rd., Suite 200 West  
Schaumburg, IL 60173

**7. AGENT SIGNATURE**

DATE: April 28, 2010

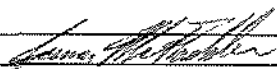
**8. COMPANY CONTACT: James J. McFadden PHONE: 847-330-5369**

## Response to DCI for PBO; 2724-796, RF2042 [CDSO]

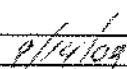
	Guideline Name	Response	Comment
830.1550	Product identity and composition	6	
830.1600	Description of materials used to produce the product	6	
830.1620	Description of production process	NR	
830.1650	Description of formulation process	6	
830.1670	Discussion of formation of impurities	6	
830.1700	Preliminary analysis	NR	
830.1750	Certified limits	6	
830.1800	Enforcement analytical method	6	
830.6302	Color	6	
830.6303	Physical State	6	
830.6304	Odor	6	
830.6313	Stability to sunlight, temperature, metals and metal ions	NR	
830.6314	Oxidizing or reducing action	NA	Product does not contain oxidizing or reducing agent
830.6315	Flammability	6	
830.6316	Explosibility	NA	Product is not potentially explosive
830.6317	Storage stability of product	6	
830.6319	Miscibility	NA	Product not to be diluted
830.6320	Corrosion characteristics	6	
830.6321	Dielectric breakdown voltage	NA	Product not applied near elect. equipment
830.7000	pH of water solutions or suspensions	NA	Product not a water solution
830.7050	UV/Visible absorption	NR	
830.7100	Viscosity	6	
830.7200	Melting point/melting point range	NR	
830.7220	Boiling point/boiling range	NR	
830.7300	Density/relative density	6	
830.7370	Dissociation constant in water	NR	
830.7550	Partition coefficient, shake flask method	NR	
830.7570	Partition coefficient, estimation by liquid chromatography	NR	
830.7840	Water solubility; column elution/shake flask method	NR	
830.7860	Water solubility; generator column method	NR	
830.7950	Vapor pressure	NR	
870.1100	Acute oral toxicity	6	
870.1200	Acute dermal toxicity	6	
870.1300	Acute inhalation toxicity	6	
870.2400	Acute eye irritation	6	
870.2500	Acute dermal irritation	6	
870.2600	Skin sensitization	6	
870.7200	Companion animal safety	6	

Note: NR is used to distinguish guidelines that are not required because of the type of test substance;  
 NA is used to distinguish guidelines that are not applicable due to the nature of the EP formulation or use.

Certified By:



Date:







RE: EPA Reg. Nos. 2724-769, 2724-668, and 2724-796 under the PBO PDCI  
James McFadden to: Julia Stokes

07/07/2010 12:36 PM

Julia -

In regards to:

2. EPA Reg No. 2724-796

Wellmark stated that a 3-Year Study is under way for Guideline 830.6317 & 830.6320 and that Wellmark would submit the 2-year study for this product which was to become available at the beginning of May 2010. Please submit this study within 10 days so that this will be a part of the product chemistry review underway.

This was submitted - see:

48089001 Johnson, D. (2010) Storage Stability and Package Compatibility of 2042 [CDSO] Topical: Final Report. Project Number: 3276, N540. Unpublished study prepared by Wellmark International. 22 p.

Trade Secret Status: Document Contains CBI

Submitter: WELLMARK INTERNATIONAL

Submitter No. Submission Date Accession No.  
002724 05/10/10 480890 01

Administrative No: 002724-796

Laboratory No.: 085514 WELLMARK INTERNATIONAL

James McFadden  
Sr. Regulatory Project Manager  
Wellmark International  
Central Life Sciences

Tel: 847-330-5369

-----Original Message-----

From: Stokes.Julia@epamail.epa.gov [mailto:Stokes.Julia@epamail.epa.gov]

Sent: Tuesday, July 06, 2010 2:59 PM

To: James McFadden

Subject: RE: EPA Reg. Nos. 2724-769, 2724-668, and 2724-796 under the PBO PDCI

Jim,

I have noticed that certain items remain outstanding or need to be responded too.

1. EPA Reg. No. 2724-668

Wellmark stated that a possible mistake was made with regard to the MRID citation for Guidelines 830.6317 & 830.6320 and that they meant to cite a similar product. Submit this citation on a revised data matrix and send an offer to pay for this citation within 10 days or conduct new studies.

2. EPA Reg No. 2724-796

Wellmark stated that a 3-Year Study is under way for Guideline 830.6317 & 830.6320 and that Wellmark would submit the 2-year study for this product which was to become available at the beginning of May 2010.

Please submit this study within 10 days so that this will be a part of the product chemistry review underway.

3. EPA Reg. No. 2724-769 FYI  
Guidelines 830.6317 & 830.6320 due to the Agency on August 15, 2010

CONFIRM RECEIPT of this EMAIL  
(ALL Confidential Business Information (CBI) MUST be mailed to the Agency via Document Processing Desk)

Thank you,  
Julia M. Stokes

Chemical Review Manager  
Risk Management and Implementation Branch (RMIB5)  
Pesticide Re-Evaluation Division (7508P)  
EPA/OPPTS/OPP  
(703) 347-8966  
stokes.julia@epa.gov

Visit: <http://www.epa.gov/pesticides>

From: James McFadden <jmcfadden@central.com>  
To: Julia Stokes/DC/USEPA/US@EPA  
Date: 07/02/2010 03:43 PM  
Subject: RE: 2724-769

Julia -  
I'm cleaning up old messages - sorry for the delay.

I hope you have a good holiday.

Regards,

James McFadden  
Sr. Regulatory Project Manager  
Wellmark International  
Central Life Sciences

Tel: 847-330-5369

-----Original Message-----

From: Stokes.Julia@epamail.epa.gov [mailto:Stokes.Julia@epamail.epa.gov]  
Sent: Tuesday, June 15, 2010 7:14 AM  
To: James McFadden  
Subject: Re: 2724-769

Good Morning Jim,  
Sorry about the crazy Monday...The MRIDs you stated in this email should be submitted on a revised data matrix. You can send this to me in email

if you like. I also need the 3-Month interim report for GL 830.6317 & 6320 for 2724-769, 2724-668, and 2724-796.

Also, the data matrices for the (12 products) in Group 1.

CONFIRM RECEIPT of this EMAIL  
(ALL Confidential Business Information (CBI) MUST be mailed to the Agency via Document Processing Desk)

Thank you,  
Julia M. Stokes

Chemical Review Manager  
Risk Management and Implementation Branch (RMIB5)  
Pesticide Re-Evaluation Division (7508P)  
EPA/OPPTS/OPP  
(703) 347-8966  
stokes.julia@epa.gov

Visit: <http://www.epa.gov/pesticides>

From: James McFadden <jmcfadden@central.com>  
To: Julia Stokes/DC/USEPA/US@EPA  
Date: 06/14/2010 04:17 PM  
Subject: 2724-769

Julia -  
Is this the information you needed for 2724-769?

48079600 Wellmark International (2010) Submission of Product Chemistry Data  
in Support of the Piperonyl Butoxide and Linalool Containing  
Product Pest Control Products Demize E.C. Transmittal of 2 Studies.  
Trade Secret Status: Document Contains CBI  
Submitter: WELLMARK INTERNATIONAL  
Submitter No. Submission Date Accession No.  
002724 04/29/10 480796 00

48079601 McDaniel, J. (2010) Pest Control Products Demize E.C.:  
Description of Materials and Formulation Process: Final Report. Project  
Number : 3743. Unpublished study prepared by Wellmark International.  
8 p

Trade Secret Status: CBI Document, Confidential A

Submitter: WELLMARK INTERNATIONAL

Submitter No. Submission Date Accession No.

002724 04/29/10 480796 01

Administrative No: 002724-769

48079602 Witte, J. (2010) Physical State, Density, Flammability and Viscosity

of Demize EC RF2110: Final Report. Project Number: 3685, N998.

Unpublished study prepared by Wellmark International. 10 p.

Trade Secret Status: Document Contains CBI

Submitter: WELLMARK INTERNATIONAL

Submitter No. Submission Date Accession No.

002724 04/29/10 480796 02

Administrative No: 002724-769

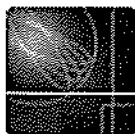
James McFadden  
Sr. Regulatory Project Manager  
Wellmark International  
Central Life Sciences

Tel: 847-330-5369

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[attachment "2724-769.pdf" deleted by Julia Stokes/DC/USEPA/US]

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To: James McFadden <jmcfadden@central.com>,  
Cc:  
Bcc:  
Subject: RE: EPA Reg. NOs. 2724-769, 2724-668, and 2724-796 under the PBO PDCI  
From: Julia Stokes/DC/USEPA/US - Friday 07/02/2010 03:43 PM

---

Jim,

I have noticed that certain items remain outstanding or need to be responded too.

1. EPA Reg. No. 2724-668

Wellmark stated that a possible mistake was made with regard to the MRID citation for Guidelines 830.6317 & 830.6320 and that they meant to cite a similar product. Submit this citation on a revised data matrix and send an offer to pay for this citation within 10 days or conduct new studies.

2. EPA Reg No. 2724-796

Wellmark stated that a 3-Year Study is under way for Guideline 830.6317 & 830.6320 and that Wellmark would submit the 2-year study for this product which was to become available at the beginning of May 2010. Please submit this study within 10 days so that this will be a part of the product chemistry review underway.

3. EPA Reg. No. 2724-769 FYI

Guidelines 830.6317 & 830.6320 due to the Agency on August 15, 2010

CONFIRM RECEIPT of this EMAIL

(ALL Confidential Business Information (CBI) MUST be mailed to the Agency via Document Processing Desk)

Thank you,  
Julia M. Stokes

Chemical Review Manager  
Risk Management and Implementation Branch (RMIB5)  
Pesticide Re-Evaluation Division (7508P)  
EPA/OPPTS/OPP  
(703) 347-8966  
stokes.julia@epa.gov

Visit: <http://www.epa.gov/pesticides>

---

James McFadden      Julia - I'm cleaning up old messages - sorry for t...

07/02/2010 03:43:59 PM

---

From: James McFadden <jmcfadden@central.com>  
To: Julia Stokes/DC/USEPA/US@EPA  
Date: 07/02/2010 03:43 PM  
Subject: RE: 2724-769

---

Julia -

I'm cleaning up old messages - sorry for the delay.

I hope you have a good holiday.

Regards,

James McFadden

Sr. Regulatory Project Manager  
Wellmark International  
Central Life Sciences

Tel: 847-330-5369

-----Original Message-----

From: Stokes.Julia@epamail.epa.gov [mailto:Stokes.Julia@epamail.epa.gov]  
Sent: Tuesday, June 15, 2010 7:14 AM  
To: James McFadden  
Subject: Re: 2724-769

Good Morning Jim,  
Sorry about the crazy Monday...The MRIDs you stated in this email should be submitted on a revised data matrix. You can send this to me in email if you like. I also need the 3-Month interim report for GL 830.6317 & 6320 for 2724-769, 2724-668, and 2724-796.

Also, the data matrices for the (12 products) in Group 1.

CONFIRM RECEIPT of this EMAIL  
(ALL Confidential Business Information (CBI) MUST be mailed to the Agency via Document Processing Desk)

Thank you,  
Julia M. Stokes

Chemical Review Manager  
Risk Management and Implementation Branch (RMIB5)  
Pesticide Re-Evaluation Division (7508P)  
EPA/OPPTS/OPP  
(703) 347-8966  
stokes.julia@epa.gov

Visit: <http://www.epa.gov/pesticides>

From: James McFadden <jmcfadden@central.com>  
To: Julia Stokes/DC/USEPA/US@EPA  
Date: 06/14/2010 04:17 PM  
Subject: 2724-769

Julia -  
Is this the information you needed for 2724-769?

48079600 Wellmark International (2010) Submission of Product Chemistry Data  
in Support of the Piperonyl Butoxide and Linalool Containing  
Product Pest Control Products Demize E.C. Transmittal of 2 Studies.

Trade Secret Status: Document Contains CBI

Submitter: WELLMARK INTERNATIONAL

Submitter No. Submission Date Accession No.  
002724 04/29/10 480796 00

48079601 McDaniel, J. (2010) Pest Control Products Demize E.C.:

Description

of Materials and Formulation Process: Final Report. Project  
Number : 3743. Unpublished study prepared by Wellmark International.  
8 p

Trade Secret Status: CBI Document, Confidential A

Submitter: WELLMARK INTERNATIONAL

Submitter No. Submission Date Accession No.  
002724 04/29/10 480796 01

Administrative No: 002724-769

48079602 Witte, J. (2010) Physical State, Density, Flammability and  
Viscosity

y of Demize EC RF2110: Final Report. Project Number: 3685,  
N998. Unpublished study prepared by Wellmark International. 10 p.

Trade Secret Status: Document Contains CBI

Submitter: WELLMARK INTERNATIONAL

Submitter No. Submission Date Accession No.  
002724 04/29/10 480796 02

Administrative No: 002724-769

James McFadden  
Sr. Regulatory Project Manager  
Wellmark International  
Central Life Sciences

Tel: 847-330-5369

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RE: PBO 8-Month Responses

James McFadden

to:

Julia Stokes

04/30/2010 12:19 PM

Cc:

Richard Moorman

Show Details

Julia -

Thank you for your call and e-mail of last Thursday. (I don't think I received the previous phone message on this topic.)

In response to your information requests, there are several issues that need discussion.

1. The product chemistry and manufacturing and materials reports for 2724-769 are complete and the reports will be sent to the EPA this week. I don't expect any issues with those reports.

2. The stability study for 2724-796 is actually approaching the three year data point - I am told I will have an interim report with 2 years of data available by the end of the week. (At which point it will be submitted.)

3. However, in regards to the stability study for 2724-769, there is an issue that needs some discussion. With existing commercial products (including this one) we have sometimes not conducted a formal guideline study, but have instead submitted a test of the stability of the existing commercial product. The EPA has, in the past, always accepted this study as a substitute for the guideline requirement. We have the samples in house, and the 1 year data point is expected to be in August of 2010. However, since this is not a guideline study, we can confirm that the study is scheduled, but no interim report will be available. Please let me know if this response will not be acceptable, and what you will need for this product.

4. In regards to the stability study for 2724-668, I will have to review the data matrix for that product. It is possible I meant to cite the stability study for a closely related formula.

Regards,

James McFadden

Regulatory Project Manager

Wellmark International

Central Life Sciences

Tel: 847-330-5369

-----Original Message-----

From: Stokes.Julia@epamail.epa.gov [mailto:Stokes.Julia@epamail.epa.gov]

Sent: Thursday, April 22, 2010 11:06 AM

To: James McFadden

Subject: PBO 8-Month Responses

Good Afternoon Jim,

I am presently working on your PBO 8-Month Responses. There are a few items missing from your submissions.

Please submit these items within 10 days of receipt of this email.

1. EPA Reg. No. 2724-668 -Submit a 3-Month Interim report on the Storage Stability and Corrosion Characteristics Study presently underway.

2. EPA Reg. No. 2724-769 -Submit a 3-Month Interim report on the Storage Stability and Corrosion Characteristics Study presently underway.

-Submit or cite guidelines 830.6302 through

830.7300

3. EPA Reg. No. 2724-796 -Submit a 3-Month Interim report on the Storage Stability and Corrosion Characteristics Study presently underway.

4. Submit data matrices for (12) products in Group 1 on letter dated 3-19-10.

CONFIRM RECEIPT of this EMAIL

(ALL Confidential Business Information (CBI) MUST be mailed to the Agency via Document Processing Desk)

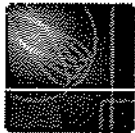
Thank you,  
Julia M. Stokes

Chemical Review Manager  
Risk Management and Implementation Branch (RMIB5)  
Pesticide Re-Evaluation Division (7508P)  
EPA/OPPTS/OPP  
(703) 347-8966  
stokes.julia@epa.gov

Visit: <http://www.epa.gov/pesticides>

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To: James McFadden <jmcfadden@central.com>,  
Cc:  
Bcc:  
Subject: Re: 2724-769  
From: Julia Stokes/DC/USEPA/US - Monday 06/14/2010 04:17 PM

---

Good Morning Jim,  
Sorry about the crazy Monday...The MRIDs you stated in this email should be submitted on a revised data matrix. You can send this to me in email if you like. I also need the 3-Month interim report for GL 830.6317 & 6320 for 2724-769, 2724-668, and 2724-796.

Also, the data matrices for the (12 products) in Group 1.

CONFIRM RECEIPT of this EMAIL  
(ALL Confidential Business Information (CBI) MUST be mailed to the Agency via Document Processing Desk)

Thank you,  
Julia M. Stokes

Chemical Review Manager  
Risk Management and Implementation Branch (RMIB5)  
Pesticide Re-Evaluation Division (7508P)  
EPA/OPPTS/OPP  
(703) 347-8966  
stokes.julia@epa.gov

Visit: <http://www.epa.gov/pesticides>

James McFadden      Julia - Is this the information you needed for 272...      06/14/2010 04:17:08 PM

---

From: James McFadden <jmcfadden@central.com>  
To: Julia Stokes/DC/USEPA/US@EPA  
Date: 06/14/2010 04:17 PM  
Subject: 2724-769

---

Julia ~  
Is this the information you needed for 2724-769?

48079600 Wellmark International (2010) Submission of Product Chemistry Data in Support of the Piperonyl Butoxide and Linalool Containing Product Pest Control Products Demize E.C. Transmittal of 2 Studies.

Trade Secret Status: Document Contains CBI

Submitter: WELLMARK INTERNATIONAL  
Submitter No. Submission Date Accession No.  
002724 04/29/10 480796 00

48079601 McDaniel, J. (2010) Pest Control Products Demize E.C.: Description of Materials and Formulation Process: Final Report. Project Number : 3743. Unpublished study prepared by Wellmark International. 8 p

Trade Secret Status: CBI Document, Confidential A

Submitter: WELLMARK INTERNATIONAL

Submitter No. Submission Date Accession No.  
002724 04/29/10 480796 01

Administrative No: 002724-769

48079602 Witte, J. (2010) Physical State, Density, Flammability and Viscosity of Demize EC RF2110: Final Report. Project Number: 3685, N998. Unpublished study prepared by Wellmark International. 10 p.

Trade Secret Status: Document Contains CBI

Submitter: WELLMARK INTERNATIONAL

Submitter No. Submission Date Accession No.  
002724 04/29/10 480796 02

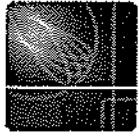
Administrative No: 002724-769

James McFadden  
Sr. Regulatory Project Manager  
Wellmark International  
Central Life Sciences

Tel: 847-330-5369

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To: "McFadden, James" <jmcfadden@central.com>,  
Cc:  
Bcc:  
Subject: PBO 8-Month Responses  
From: Julia Stokes/DC/USEPA/US - Thursday 04/22/2010 11:49 AM

Good Afternoon Jim,

I am presently working on your PBO 8-Month Responses. There are a few items missing from your submissions.

Please submit these items within 10 days of receipt of this email.

1. EPA Reg. No. 2724-668 -Submit a 3-Month Interim report on the Storage Stability and Corrosion Characteristics Study presently underway.

2. EPA Reg. No. 2724-769 -Submit a 3-Month Interim report on the Storage Stability and Corrosion Characteristics Study presently underway.

-Submit or cite guidelines 830.6302 through 830.7300

3. EPA Reg. No. 2724-796 -Submit a 3-Month Interim report on the Storage Stability and Corrosion Characteristics Study presently underway.

4. Submit data matrices for (12) products in Group 1 on letter dated 3-19-10.

CONFIRM RECEIPT of this EMAIL


(ALL Confidential Business Information (CBI) MUST be mailed to the Agency via Document Processing Desk)

Thank you,  
Julia M. Stokes

Chemical Review Manager  
Risk Management and Implementation Branch (RMIB5)  
Pesticide Re-Evaluation Division (7508P)  
EPA/OPPTS/OPP  
(703) 347-8966  
stokes.julia@epa.gov

Visit: <http://www.epa.gov/pesticides>

[jinciadden@central.com](mailto:jinciadden@central.com)  
[www.centrallifesciences.com](http://www.centrallifesciences.com)

  
James McFadden, Ph.D.  
Sr. Regulatory Project Manager

1	2	3	4	5	6	7	8	9	10
11	12	13	14	15	16	17	18	19	20
21	22	23	24	25	26	27	28	29	30
31	32	33	34	35	36	37	38	39	40
41	42	43	44	45	46	47	48	49	50
51	52	53	54	55	56	57	58	59	60
61	62	63	64	65	66	67	68	69	70
71	72	73	74	75	76	77	78	79	80
81	82	83	84	85	86	87	88	89	90
91	92	93	94	95	96	97	98	99	100

## TRANSMITTAL DOCUMENT

## 1. NAME AND ADDRESS OF SUBMITTER

Wellmark International  
1501 E. Woodfield Road  
Suite 200 West  
Schaumburg, IL 60173

## 2. REGULATORY ACTION SUPPORTED BY THIS SUBMISSION

Submission of Reports to Support Data Call-In Requirements for  
EPA Reg. No. 2724-796, RF2042 [CDSO]

## 3. TRANSMITTAL DATE

May 7, 2010

## 4. LIST OF DOCUMENTS SUBMITTED

- 48089001** 1. Johnson, D. (2010) Storage Stability and Package Compatibility of RF2042 [CDSO] Topical,  
EPA Reg. # 2724-796, unpublished, Wellmark International Study No. 3276, 22 pp.

## 5. COMPANY NAME

Wellmark International

## 6. COMPANY AGENT

James McFadden  
Regulatory Project Manager  
Wellmark International  
1501 E. Woodfield Rd., Suite 200 West  
Schaumburg, IL 60173

## 7. AGENT SIGNATURE



DATE: May 7, 2010

## 8. COMPANY CONTACT: James J. McFadden PHONE: 847-330-5369



Wellmark™

2724-796

✓ 4-570

James McFadden, Ph.D.

Regulatory Project Manager

Wellmark International

1501 E. Woodfield Rd

Suite 200W

Schaumburg, IL 60173

847-330-5369 phone

847-330-5391 fax

jmcadden@central.com

www.centrallifesciences.com

March 19, 2010

Julia Stokes, CRM

Product Re-evaluation Division

Document Processing Desk (DCI-PRD-2525)

Office of Pesticide Programs (7508P)

U.S. Environmental Protection Agency

Room S-4900, One Potomac Yard

2777 South Crystal Drive

Arlington VA 22202

**Subject: Eight Month Response to Product Specific Data Call-In: PDCI-067501-26956**  
**Wellmark Products Containing PBO**  
**(Contains Confidential Business Information)**

Dear Ms. Stokes:

Enclosed please find Wellmark International's Eight Month Response to the product specific DCIs for products containing PBO (PDCI-067501-26956). In our 90-day response, Wellmark proposed our response for the products, and has received no further discussion from the EPA on the method of support.

A Supplemental Response was also submitted that contained those products that could be streamlined with the PDCI for Pyrethrins (Dec. 14, 2009). Excluding products that have been streamlined with the Pyrethrins DCI, there are twenty-two products remaining that require a response, and those twenty-two products are listed in the table below:

APR 05 2010

2724-636	SPEER NEOPERM TOTAL RELEASE INDOOR FOGGER
2724-637	SPEER NEOPERM YARD & PATIO
2724-638	SPEER NEOPERM HOUSEHOLD CRAWLING INSECT KILLER
2724-639	SPEER NEOPERM INDUSTRIAL CRAWLING INSECT KILLER
2724-640	SPEER NEOPERM WASP & HORNET KILLER #1
2724-641	SPEER NEOPERM WASP & HORNET KILLER #2
2724-643	SPEER NEOPERM CRAWLING INSECT KILLER I
2724-644	SPEER NEOPERM CRAWLING INSECT KILLER II
2724-645	SPEER NEOPERM CRAWLING INSECT KILLER III
2724-646	SPEER NEOPERM CRAWLING INSECT KILLER IV
2724-648	SPEER NEOPERM TOTAL RELEASE INDOOR FOGGER IV
2724-669	SPEER NEOPERM FLYING INSECT KILLER
2724-698	<del>TETRAPERM WASP &amp; HORNET KILLER FEQ 23 II</del> <b>- To be canceled</b>
2724-490	RF 9910 AEROSOL
2724-667	CRAWLING INSECT KILLER I
2724-668	FLYING INSECT KILLER II
2724-677	YARD & PATIO FOGGER
2724-699	CRAWLING INSECT KILLER II
2724-769	PEST CONTROL PRODUCTS DEMIZE E.C.
2724-786	RF2050 SPRAY
2724-796	RF 2042 (CDSO)
2724-797	RF2063 PET SPRAY

The table is arranged in 3 groups:

1. The first group of products (2724-636 to 2724-669) are me-too products of existing registrations of Valent Biosciences. [REDACTED] The letter of authorization is not available yet, but is forthcoming. In part, due to delays, we also do not have a data matrix for these products. But we also expect that the data matrix will be supplied in the near future.
2. The second group is represented by one product, 2724-698. We have decided that we now intend to cancel this product, and no further support is provided for this product.
3. The third group of products, 2724-490 to 2724-797, represent products that Wellmark is actively defending, and a full response is provided for these products. In the case where reports are expected to support these products, those reports will be sent under separate cover within a week or so.

The 8-month response for each of the twenty-one products that are supported is enclosed with this letter and contains:

Form 8570-1, Application for Pesticide Re-Registration  
 Revised Label, 5 copies  
 Form 8570-4, Confidential Statement of Formula, 2 copies  
 Form 8570-27, Formulator's Exemption Statement, 1 copy  
 Form 8570-34 Certification with respect to Citations of Data  
 Form 8570-35, Data Matrix for Each product. (except for Valent me-too products)

\*Product ingredient source information may be entitled to confidential treatment\*

In several cases (2724-490, 2724-796 and 2724-797) we also include the data matrix for technical (S)-Methoprene, since we are the technical registrant and the data requirements are not covered by the Formulator's Exemption Statement.

In another case (2724-769, the Demize EC) we also include the data matrix for technical Linalool, since we are one of the technical registrants (2724-762) and the data requirements are not covered by the Formulator's Exemption Statement.

If you have questions regarding our plans to support these products, or require further information, please let me know.

Regards,



James McFadden, Ph.D.  
Regulatory Project Manager

October 15, 2009

Julia Stokes, CRM  
Product Re-evaluation Division  
Office of Pesticide Programs (7508P)  
U.S. Environmental Protection Agency  
Room S-4900, One Potomac Yard  
2777 South Crystal Drive  
Arlington VA 22202

Subject: **Submission of 90-Day DCI Response for Piperonyl Butoxide  
PDCI-067501-26956  
(Contains Confidential Business Information)**

Dear Ms. Stokes:

Enclosed with this letter please find Wellmark International's Response to the PBO End Use Product Data Call-In (PDCI-067501-26956). Out of a total of 156 products involved in this DCI, Wellmark is cancelling 102 registrations, and will support 54 products for re-registration.

However, note that there are two groups of products in the products supported for re-registration:

- Group 1 products are current commercial products that are very important to us, and represent a priority for support. For these products, I have provided a summary sheet that describes how we intend to support these products.
- Group 2 products are mostly non-commercial products [REDACTED]

[REDACTED] In each case, the Wellmark registration that is being supported is a me-too (substantially similar) to the Valent or MGK product. When we supply a data matrix with the 8-month response, we will also supply a letter of authorization.

There are also a few additional details involved in this response, as described in the paragraphs below:

Wellmark is working with Valent Biosciences to provide new companion animal safety studies to support our pet products. Actually, several studies will be conducted to support our permethrin spot-on products and pet sprays and shampoos. Study outlines and initial discussions were held with the EPA

*JK*  
OCT 20 2009

United States Environmental Protection  
Agency Washington, D.C. 20460

OMB Approval 2070-0107  
OMB Approval 2070-0057

DATA CALL-IN RESPONSE

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form.  
Use additional sheet(s) if necessary

1. Company Name and Address WELLMARK INTERNATIONAL 1501 E. WOODFIELD ROAD, SUITE 200 WEST SCHAUMBURG, IL 60173		2. Case # and Name 2525 Piperonyl butoxide Chemical # and Name 067501 Piperonyl butoxide		3. Date and Type of DCI and Number 19-May-2009 PRODUCT SPECIFIC ID # PDCI-067501-26956	
EPA Product Registration	5. I wish to cancel this product regis- tration volun- tarily	6. Generic Data		7. Product Specific Data	
		6a. I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA regis- tration number listed below.	6b. I agree to satisfy Generic Data requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response."	7a. My product is an MUP and I agree to satisfy the MUP requirements on the attached form entitled "Requirements Status and Registrant's Response."	7b. My product is an EUP and I agree to satisfy the EUP requirements on the attached form entitled "Requirements Status and Registrant's Response."
2724-790		N.A.	N.A.		✓ ✓ ✓ ✓
2724-792		N.A.	N.A.		
2724-796		N.A.	N.A.		
2724-797		N.A.	N.A.		
Initial to indicate certification as to information on this page (full text of certification is on page one).			Date		

JdM

10/12/09

United States Environmental Protection  
Agency Washington, D.C. 20460

OMB Approval 2070-0107  
OMB Approval 2070-0057

**REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE**

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form.  
Use additional sheet(s) if necessary.

1. Company Name and Address WELLMARK INTERNATIONAL 1501 E. WOODFIELD ROAD, SUITE 200 WEST SCHAUMBURG, IL 60173		2. Case # and Name 2525 Piperonyl butoxide  EPA Reg. No. 2724-796			3. Date and Type of DCI and Number 19-May-2009 PRODUCT SPECIFIC ID # PDCI-067501-26956				
4. Guideline requirement number	5. Study Title	P R O T O C O L	Progress Reports			6. Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registrant Response
			1	2	3				
	<b>Product Chemistry Data Requirements (Conventional Chemical)</b>								
830.1550	Product Identity and composition (40)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI/MP/EP	8	6
830.1600	Description of materials used to produce the product (42)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI/MP/EP	8	6
830.1620	Description of production process (43)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI	8	NR
830.1650	Description of formulation process (44)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	MP/EP	8	6
830.1670	Discussion of formation of impurities (45)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI/MP/EP	8	6
830.1700	Preliminary analysis (1, 2, 41)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI	8	NR
830.1750	Certified limits (46)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI/MP/EP	8	6
830.1800	Enforcement analytical method (47)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI/MP/EP	8	6
830.6302	Color (3)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI/MP/EP	8	6
830.6303	Physical state (4)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI/MP/EP	8	6
830.6304	Odor (5)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI/MP/EP	8	6
10. Certification I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law							11. Date 9/14/09		
Signature and Title of Company's Authorized Representative <i>James M. Koblus, Regulatory Project Mgr.</i>									
12. Name of Company <i>Wellmark International</i>							13. Phone Number <i>(847)-330-5369</i>		

United States Environmental Protection  
Agency Washington, D.C. 20460

OMB Approval 2070-0107  
OMB Approval 2070-0057

**REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE**

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form.  
Use additional sheet(s) if necessary.

1. Company Name and Address  WELLMARK INTERNATIONAL 1501 E. WOODFIELD ROAD, SUITE 200 WEST SCHAUMBURG, IL 60173		2. Case # and Name  2525 Piperonyl butoxide  EPA Reg. No. 2724-796		3. Date and Type of DCI and Number  19-May-2009 PRODUCT SPECIFIC ID # PDCI-067501-26956					
4. Guideline requirement number	5. Study Title	P R O T O C O L	Progress Reports			6. Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registrant Response
			1	2	3				
830.7220	Boiling point/boiling range (18,19)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI	8	NR
830.7300	Density/relative density (20,21)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI/MP/EP	8	6
830.7370	Dissociation constant in water (22,23)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI or PAI	8	NR
830.7550	Partition coefficient (n-octanol/water), shake flask method (24)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI/PAI	8	NR
830.7570	Partition coefficient (n-octanol/water), estimation by liquid chromatography (25)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI/PAI	8	NR
830.7840	Water solubility: Column elution method, shake flask method (26)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI or PAI	8	NR
860	Water solubility, generator column method (27)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI or PAI	8	NR
830.7950	Vapor pressure (28,29)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI or PAI	8	NR
<b>Toxicology Data Requirements (Conventional Chemical)</b>									
870.1100	Acute Oral Toxicity (30,51)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI,EP,dilute EP?	8	6
870.1200	Acute dermal toxicity (31,32,52)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI,EP,dilute EP?	8	6
870.1300	Acute inhalation toxicity (33)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI & EP	8	6
Initial to indicate certification as to information on this page (full text of certification is on page one).							Date 9/14/09		



United States  
**Environmental Protection Agency**  
 Washington, DC 20460  
**Formulator's Exemption Statement**  
 (40 CFR 152.85)

Applicant's Name and Address <b>Wellmark International</b> 1501 E. Woodfield Road, Suite 200 West Schaumburg, IL, 60173	EPA File Symbol/Registration Number <b>2724-796</b>
	Product Name <b>RF2042 (CDSO)</b>
	Date of Confidential Statement of Formula (EPA Form 8570-4) <b>08/15/2008</b>

As an authorized representative of the applicant for registration of the product identified above, I certify that:

(1) This product contains the following active ingredient(s):

Etofenprox, CAS# 80844-07-1  
 Piperonyl Butoxide, CAS# 51-03-6  
 (S)-Methoprene, CAS# 65733-16-6

(2) **Of** these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another person and meets the requirements of 40 CFR section 158.50(e)(2) or (3).

(3) Indicate by checking (A) or (B) below which paragraph applies:

☐ (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

☒ (B) The Confidential Statement of Formula (CSF)(EPA Form 8570-4) referenced above and on file with the EPA is complete, current, an accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

Source		
Active Ingredient	Product Name	Registration Number
Piperonyl Butoxide		
Etofenprox		
Signature	Name and Title	Date
	James McFadden, Reg. Project Mgr	03/19/2010

EPA Form 8570-27 (Rev. 06-2004)

Copy 1 - EPA  
 Copy 2 - Applicant copy

\*Product ingredient source information may be entitled to confidential treatment\*





**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
**1200 Pennsylvania Avenue, N.W.**  
**WASHINGTON, D.C. 20460**

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reviewing the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, Collection Strategies Division (2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. Do not send the completed form to this address.

**Certification with Respect to Citation of Data**

Applicant's/Registrant's Name, Address, and Telephone Number Wellmark International, 1501 E. Woodfield Rd., Suite 200 West, Schaumburg, IL, (847) 330-5369	EPA Registration Number/File Symbol 2724-796
Active Ingredient(s) and/or representative test compound(s) S-Methoprene, PBO, Etofenprox	Date March 19, 2010
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Pets and Domestic Animals	Product Name RF2042 (CDSO)

**NOTE:** If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

**SECTION I: METHOD OF DATA SUPPORT (Check one method only)**

<input type="checkbox"/> I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).	<input checked="" type="checkbox"/> I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).
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**SECTION II: GENERAL OFFER TO PAY**

(Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements)

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

**SECTION III: CERTIFICATION**

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature 	Date March 19, 2010	Typed or Printed Name and Title James McFadden, Regulatory Project Mgr.
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United States  
Environmental Protection Agency  
Washington, DC 20460

☒ Registration  
☐ Amendment  
☐ Other

OPP Identifier Number

## Application for Pesticide - Section I

1. Company/Product Number Wellmark International/2724-796	2. EPA Product Manager M. Suarez	3. Proposed Classification  <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Wellmark International/RF2402 (CDSO)	PM # 13	
5. Name and Address of Applicant / Registrant (Include ZIP Code) Wellmark International 1501 East Woodfield Road, Suite 200 West Schaumburg, Illinois 60173  <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(C)(3) (b)(i), my product is similar or identical in composition and labeling to:  EPA Reg. No _____ Product Name _____	

## Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application
<input type="checkbox"/> Notification - Explain below.	<input checked="" type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and section II.)

Application for Re-registration submitted as part of our response to End-use Product DCIs. This form is submitted with our 8-month response for products involved in the PBO Reregistration DCI (PDCI-069001-26530). Applicable forms are enclosed with the submission. For questions, contact: James McFadden; Tel: (847) 330-5369, Fax: (847) 330-5369; E-Mail: jmcfadden@central.com

## Section - III

1. Material This Product Will be Packaged In:				2. Type of Container	
Child-Resistant Packaging  <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging  <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging  <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	
				<input checked="" type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input checked="" type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
* Certification must be submitted					
3. Location of Net Contents Information  <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) Retail Container 1.5/3/4.5/6 cc applicators	5. Location of Label Directions  <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Label Accompanying Product			
6. Manner in Which Label is Affixed to Product  <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input checked="" type="checkbox"/> Other printed on cardboard carton			

## Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name James McFadden	Title Regulatory Project Manager	Telephone No. (Include Area Code) (847) 330-5369
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statements may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received  (Stamped)
2. Signature 	3. Title Regulatory Project Manager	
4. Typed Name James McFadden	5. Date March 19, 2010	